U.S. DEPARTMENT OF COMMERCE
National Technical Information Service
PB-279 535

Analytical Studies for the U.S. Environmental Protection Agency Volume VII. Pesticide Decision Making

National Research Council, Washington, D C

Prepared for

Environmental Protection Agency, Washington, D C

Jan 78

PB 279 535

ANALYTICAL STUDIES FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY

VOLUME VII

Pesticide Decision Making

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SPRINGFIELD, VA. 22161

BIBLIOGRAPHIC DATA SHEET	1. Report No. ISBN 0-309-02734-9	2.	3. Recipient's Accession No. PB279535
4. Title and Subtitle Pesticide Decision Making			5. Report Date Pub Date - 01/78 6.
7. Author(s) Committee on Pesticide Decision Making, National Research Council			8. Performing Organization Rept. No.
9. Performing Organization Name and Address National Academy of Sciences 2101 Constitution Avenue Washington, D.C. 20418			10. Project/Task/Work Unit No. 11. Contract/Grant No. 68-01-2430
12. Sponsoring Organization Name and Address Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460			13. Type of Report & Period Covered 14.

15. Supplementary Notes

16. Abstracts

Assesses the role of scientists & technicians in implementing the amended Federal Insecticide, and Rodenticide Act. Also reviews risk/benefit assessments in pesticide regulations; exemptions from EPA regulations; the scientific input into the administrative hearings held by EPA to determine whether the use of a pesticide should be cancelled or suspended; & EPA's conduct of its responsibility to establish tolerance for pesticide residues under the Federal Food, Drug, & Cosmetics Act.

17. Key Words and Document Analysis. 17a. Descriptors

17b. Identifiers/Open-Ended Terms

17c. COSATI Field/Group

18. Availability Statement paper copy available from NTIS	19. Security Class (This Report) UNCLASSIFIED	21. No. of Pages 125
	20. Security Class (This Page) UNCLASSIFIED	22. Price A06-A01

FORM NTIS-35 (REV. 4-72)

THIS FORM MAY BE REPRODUCED

USCOMM-DC 14952-P72

ANALYTICAL STUDIES FOR THE U.S.
ENVIRONMENTAL PROTECTION AGENCY

VOLUME VII

Pesticide Decision Making

A Report to the
U.S. Environmental Protection Agency
from the
Committee on Pesticide Decision Making

Commission on Natural Resources
National Research Council

NATIONAL ACADEMY OF SCIENCES
Washington, D.C. 1978

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NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Fesearch Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

This study was requested and funded by the U.S. Environmental Protection Agency.

Contract No. 68-01-2430

Library of Congress Catalog Card Number 77-94524

International Standard Book Number 0-309-02734-9

Available from

Printing and Publishing Office
National Academy of Sciences
2101 Constitution Avenue
Washington, D.C. 20418

Printed in the United States of America

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FOREWOPD

This report is one of a series prepared by the National Research Council for the U.S. Environmental Protection Agency.

In June 1973 the Subcommittee on Agriculture, Environmental, and Consumer Protection of the Appropriations Committee of the U.S. House of Representatives held extensive hearings on the activities of the EPA. The ensuing appropriations bill for fiscal year 1974 directed the Agency to contract with the National Academy of Sciences for a series of analytical advisory studies (87 Stat. 468, PL 93-135). EPA and the Academy agreed upon a program that would respond to the Congressional intent by exploring two major areas: the process of acquisition and use of scientific and technical information in environmental regulatory decision making; and the analysis of selected current environmental problems. The Academy directed the National Research Council to formulate an approach to the analytical studies, and the National Research Council in turn designated the Commission on Natural Pesources as the unit responsible for supervising the program.

The inside front cover of this volume lists the other studies in the series, and the inside back cover presents a diagram of the structure of the program. Each of the component studies has issued a report of its findings. Volume I of the series, Perspectives on Technical Information for Environmental Protection, is the report of the Steering Committee for Analytical Studies and the Commission on Natural Resources. It describes in detail the origins of the program and summarizes and comments on the more detailed findings and judgments in the other reports.

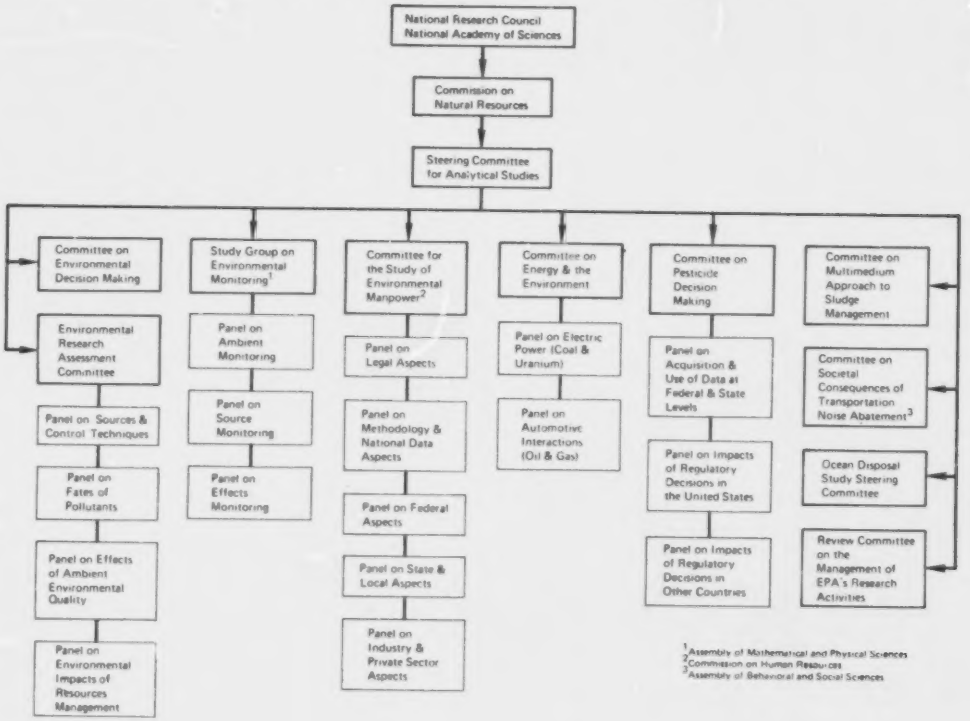
This typescript edition is an interim printing made in limited quantity. The report will be published in a typeset version during 1977, along with the rest of the series, and distributed for sale by the Printing and Publishing Office of the National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418.

Components of the NRC Program of Analytical Studies for the U.S. Environmental Protection Agency

Project	Project Chairman	Sponsoring Unit of the NRC
Steering Committee for Analytical Studies (SCAS)	R. M. Solow	Commission on Natural Resources
Environmental Decision Making (CEDM)	J. P. Ruina	Environmental Studies Board, Committee on Public Engineering Policy
Environmental Research Assessment (ERAC)	J. M. Neuhold	Environmental Studies Board
Environmental Monitoring (SGEM)	J. W. Pratt	Committee on National Statistics, Environmental Studies Board, Numerical Data Advisory Board
Environmental Manpower (CSEM)	E. F. Gloyna	Commission on Human Resources
Energy and the Environment (CEE)	S. I. Auerbach	Board on Energy Studies
Pesticide Decision Making	W. G. Eden	Board on Agriculture and Renewable Resources, Environmental Studies Board [a]
Multimedium Approach to Municipal Sludge Management	H. O. Banks	Environmental Studies Board
Societal Consequences of Transportation Noise Abatement	W. J. Baumol	Assembly of Behavioral and Social Sciences[b]
Disposal in the Marine Environment	D. S. Gorsline	Ocean Affairs Board
Review of Management of EPA's Research Activities	R. W. Berliner	Commission on Natural Resources

[a] In cooperation with the Building Research Advisory Board.
[b] In cooperation with the Building Research Advisory Board and the Transportation Research Board.

Structure of the NRC Program of Analytical Studies for the U.S. Environmental Protection Agency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Environmental Research Assessment Committee
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Panel on Effects of Ambient Environmental Quality
Panel on Environmental Impacts of Resources Management
Study Group on Environmental Monitoring[1]
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Committee for the Study of Environmental Manpower[2]
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Panel on Methodology & National Data Aspects
Panel on Federal Aspects
Panel on State & Local Aspects
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Committee on Pesticide Decision Making
Panel on Acquisition & Use of Data at Federal & State Levels
Panel on Impacts of Regulatory Decisions in the United States
Panel on Impacts of Regulatory Decisions in Other Countries
Committee on Multimedium Approach to Sludge Management
Committee on Societal Consequences of Transportation Noise Abatement[3]
Ocean Disposal Study Steering Committee
Review Committee on the Management of EPA's Research Activities
[1] Assembly of Mathematical and Physical Sciences
[2] Commission on Human Resources
[3] Assembly of Behavioral and Social Sciences

PREFACE

A central concern of the Congress in initiating a series of analytical studies by the National Academy of Sciences for EPA related to the use of chemicals to control pests in agriculture and in and around the home (U.S. Congress, House 1973). As one of these analytical studies, this report of the Committee on Pesticide Decision Making and its recommendations are directed mainly toward the EPA Office of Pesticide Programs (OPP). Most of the data considered by the Committee in preparing the report were collected in the calendar year 1976. Therefore, the reader should be cautioned that there have been recent changes in EPA's pesticide regulatory decision-making process that were being instituted in 1977 and are not covered in this report.

The two main thrusts of this study are to assess: (1) the roles of science and technology in decision making in the regulation of pesticides, and (2) the impact of policies and regulations on the availability and use of pesticides and pest control mechanisms at federal and state levels. The Committee confined its attention to pesticides because pest control through integrated pest management was considered in detail by a previous Academy committee (NRC 1975b).

EPA and the Committee agreed that this study, which was done under contract with EPA, should address these major points: the role of scientists and technicians in implementing the Federal Insecticide, Fungicide, and Rodenticide Act, as amended; the scientific input into EPA's administrative hearings which are held to determine whether the use of a pesticide should be cancelled or suspended; exemptions from EPA regulations; risk/benefit assessments in pesticide regulation; EPA's conduct of its responsibility to establish tolerances for pesticide residues under the Federal Food, Drug, and Cosmetic Act; and the adequacy of the economic data used by EPA in its regulatory decisions on crop and other losses resulting from pests or vector-borne disease. In addition, the Committee

did a limited investigation of the impact of EPA's pesticide decisions on other countries.

Three Committee panels gathered and evaluated information for certain phases of the study. These were a Federal Panel, which was concerned with EPA's acquisition and use of scientific and technical information in its decision making on pesticides; a State Panel, which was concerned with the various relationships of state agencies in the federal regulation of pesticides; and an International Panel, which was responsible for the study of the impact outside the United States of EPA decisions on pesticides. In the development of this report, the Committee and its Panels sought viewpoints and recommendations from many different groups, including environmentalists, trade associations, and professional societies. The directors of all State Agricultural Experiment Stations (SAES) and the chemical pesticide coordinator in each State Cooperative Extension Service (SCES) also were contacted. In addition, a two-day workshop was held in which papers representing diverse viewpoints were presented. The workshop papers are on file at the Board on Agriculture and Renewable Resources of the National Research Council, where they are available for public inspection.

ACKNOWLEDGMENTS

We wish to acknowledge the assistance of the following individuals who worked closely with the Committee and its staff. We are grateful for their informed opinion and experience. They include: Fred Abel, U.S. Energy Research and Development Administration; Jerome Alpert, Silver Spring, Maryland; J. Lawrence Apple, North Carolina State University; Irwin Auerbach, EPA; Lucas Brader, Food and Agriculture Organization of the United Nations; John F. Copplestone, World Health Organization; Alexander C. Davis, New York State Agricultural Experiment Station; Arlen Davison, Washington State University; Boysie Day, University of California; Errett Deck, U.S. Department of Agriculture; Terry M. Dworkin, Indiana University; K. Ross Fitzsimmons, Shell Chemical Company; Virgil H. Freed, Oregon State University; Charles N. Frommer, New York Department of Environmental Conservation; William Furtick, Food and Agriculture Organization of the United Nations; Ahmad S.K. Ghouri, Pakistan Agricultural Research Council; Ralph F. Glasser, Shell Oil Company; Ralph Heal, Oxford, Maryland; John C. Hillis, California Department of Food and Agriculture; Harold Hubbard, Pan American Health Organization; Eugene E. Kenaga, Dow Chemical Company; Ellery Knake, University of Illinois; Ronald J. Kuhr, New York State Agricultural Experiment Station; Dean F. Lovitt, Michigan Department of Agriculture; Gus Mathys, European Plant Protection Organization; Jose A. Najera, Pan American Health Organization; L. Dale Newsom, Louisiana State University; John Osmun, Purdue University; Vernon Perry, University of Florida; Donald C. Peters, Oklahoma State University; Maurice Provost, Florida State Board of Health; Charles Reese, EPA; Harold T. Reynolds, University of California; John Riss, Arlington, Virginia; Paul Schnurrenberger, Auburn University; Edward H. Smith, Cornell University; Ely Swisher, Rohn and Haas Company; Jay Turim, EPA; Fred H. Tschirley, Michigan State University; Robert P. Upchurch, University of Arizona; William Upholt, EPA; Kenneth Walker, U.S. Department of Agriculture; Edith Brown-Weiss, Princeton University; and Richard R. Whetstone, Shell Chemical Company.

We also wish to acknowledge our appreciation for the very helpful editorial assistance of Patricia Marshall and to Mary Lou Sutton for her able and tireless secretarial support. Appreciation is also due to Robert C. Pooney, Philippa Shepherd, Estelle Miller, and Claire Chow of the editorial staff who generously provided assistance in preparing this report.

SUMMARY

This report is concerned with how EPA acquires and uses scientific information in its decision-making functions for the regulation of pesticides. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA has broad and flexible authority. The Agency determines not only what compounds may be registered as pesticides but also the purposes for which they may be used and the methods of application. Additional authority for EPA's regulation of pesticides is provided by Sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act, as amended, which relate to the control of pesticide residues in food and feed products. The Office of Pesticide Programs (OPP) is the unit within EPA with the major responsibilities for regulating pesticides; other EPA units have major enforcement and research responsibilities in this area.

When OPP evaluates a pesticide and decides whether to permit its registration or reregistration or to ban or restrict its use, it must determine whether a pesticide will effectively control the target species and whether it will not result in "unreasonable adverse effects" to humans or to the environment. The unreasonable effects, which FIFRA, as amended, requires the Agency to take into account in its determinations about a pesticide, have been defined by EPA (40 CFR 162.11) in these terms: the hazard of acute toxicity in humans, domestic animals, or wildlife; the hazard of chronic toxicity (oncogenic effects are induced in humans or in experimental animals, mutagenic effects are produced in test animals, significant reductions will occur in nontarget organisms, or fatalities will occur in endangered species); or when there is no antidote or other emergency treatment for toxic effects resulting from a single exposure to the pesticide. The OPP determination of efficacy can be made on the basis of laboratory and field tests and other scientific procedures. The determination of unreasonable adverse effects is essentially an administrative determination involving the concepts of "unreasonable" and "adverse,"

rather than mathematical absolutes. Scientific knowledge and data do, however, serve as a basis for the determination of unreasonable adverse effects to the degree that it is possible to quantify and predict the risks to humans or to the environment that may occur as a result of a pesticide's use.

A major problem that EPA has encountered in the regulation of pesticides stems from questions about the adequacy of the data that the Agency uses to make the complex decisions involved in determinations of whether a pesticide is likely to cause unreasonable adverse effects, and particularly the adequacy of its data that indicate a pesticide's potential for causing cancer. Scientific investigations of the chronic effects of a pesticide, such as the potential for carcinogenicity, are relatively long-term studies that can take two to three years, may be costly to conduct, and often produce data that are suggestive rather than absolute.

Not only is this decision making complex, but it is massive in scale. FIFRA, as amended, requires that in addition to ruling on new applications for the registration of pesticides, EPA must review 33,000 pesticides that were approved under earlier and less stringent legislation. The deadline that was set by Congress for this review is October 21, 1977. EPA also must review 4000 tolerances that were set in earlier years for residues of pesticides in food and feed.

EPA is finding it impossible to implement the Congressional mandate for review of old registrations. The difficulty centers on the adequacy of the data that are needed for the reregistration process. The Agency has more than one million pieces of data in its files, going back to 1947, and it must catalog and make these data accessible for reregistration reviews. Furthermore, when OPP began reviewing some of the older pesticides for reregistration, it found that in many cases the data on these pesticides were faulty and incomplete in terms of present scientific standards and the requirements of current legislation. OPP proposed that a new category of "conditional registration" be used to permit the continued use of many of the pesticides that are currently registered and used for food and forage crops, and for structural, horticultural, forestry and other purposes. The plan was to continue these registrations on a conditional basis so that the Agency could organize and assess the data in its files, and registrants would have additional time to submit the new data required by FIFRA, as amended. The proposal met with objections in

Congress and elsewhere on the grounds that it would create a double standard, one for new pesticides and the other for older products. Questions also were raised about permitting the continued use of pesticides in the absence of data to establish whether they might create unreasonable adverse effects to humans or to the environment. As a result of these problems, EPA has halted its registration and reregistration of pesticides.

While the Committee on Pesticide Decision Making is sympathetic to the diversity and magnitude of the responsibilities of the Office of Pesticide Programs, it nevertheless believes that the urgency of the problems in pesticide regulation calls for prompt and workable procedures that can be relied upon by all concerned. This complex and difficult task must be a cooperative effort by many sectors in our society, with imaginative and positive leadership provided by EPA.

MAJOR RECOMMENDATIONS

Long-Term Data Needs

The Committee on Pesticide Decision Making believes that the need for adequate scientific data on which OPP can base its decisions is a central area of concern. FIFRA, as amended, assigns the responsibility to the applicant for the development of data to support a registration or reregistration. However, in order to assess the information that is submitted by interested parties, OPP must have access to the most complete and up-to-date scientific data available, and to knowledge based on experience in the use of particular pesticides, so that the Agency can make sound determinations of the possible risks resulting from the use of these pesticides.

Modern Data System

Some of the data needs can be met within the Agency, but others will require multiagency efforts so that there will be better coordination of data that are already available relating to the use of pesticides. (See Chapter 3.)

- OPP should take the lead in developing a modern data system to identify important sources of scientific and technical information on pesticides and to provide a

reliable method for collecting, evaluating, validating, indexing, and computerizing data on pesticides.

Research on Carcinogens

The Committee believes that a greater national commitment must be made to conduct research on carcinogens in the environment. While such an effort will not ease the immediate problems of EPA in the regulation of pesticides, it is clear that this research is essential for the longer term to address the persistent and difficult problems of carcinogenicity that arise in connection with the use of pesticides. (See Chapter 2.)

- EPA should sponsor research to obtain broad determinations of the levels of human exposure to carcinogens in the environment. In addition, a multiagency effort should be undertaken to develop national criteria for interpreting data on carcinogens, and for assessing the carcinogenic risks of human exposures to pesticides.

Risk/Benefit Assessments

The judgmental aspects of EPA decisions on pesticides are complicated further by the fact that the Agency is required by law to balance the risks that may result from the use of a pesticide with the benefits that may be derived from its use. This involves such complex issues as weighing any possible increased risks of cancer if a pesticide is approved against the needs for pest control measures in agriculture, forestry, and structural uses, and the costs of food, lumber, and buildings if damage from pests occurs. The number of people who might be affected by a decision and the possibility that some groups of people, such as field workers, might be unduly affected by some decisions also must be taken into consideration. Furthermore, there may be trade-offs that should be made between hazards to human health in using a pesticide and the numbers of people who would be protected from a vector-borne disease if that pesticide were used.

Much of the controversy regarding the use of economic analysis in guiding pesticide regulation is focused on the uncertainties in quantifying risks and benefits. The balancing of risks and benefits is a

difficult undertaking and requires the adoption of methods and administrative procedures to ensure that the most accurate scientific information available is used in making such judgments. (See Chapter 2.)

- EPA should develop detailed procedures for assessing the risks and benefits resulting from the use of a pesticide and for analyzing trade-offs between the risks and benefits. In doing so, EPA should seek outside review and comment from the scientific community.

Coordination of Data Sources

State Coordination

Much of the knowledge about the benefits to be derived from the use of a pesticide is dispersed throughout the State Agricultural Experiment Stations, which do research in agriculture, the State Cooperative Extension Services, whose educational functions keep them in close communication with the users of pesticides, state agencies that regulate pesticides, public health agencies, departments of natural resources, and other state organizations. Coordination among these groups would serve to funnel vital data on pesticide uses to EPA and, in turn, could serve as a means of communicating EPA's regulatory decisions on pesticides to user groups. (See Chapter 3.)

- State agencies regulating the registration, distribution, and use of pesticides should have a formal liaison, either through a state advisory board for pesticide regulation or through a memorandum of agreement, with these groups: the State Agricultural Experiment Stations; State Cooperative Extension Services; other state agencies; industry and trade associations; and public health, environmental, and user groups.

EPA/USDA Coordination

FIFRA, as amended, requires EPA to notify the U.S. Department of Agriculture (USDA) before issuing a notice of intent to cancel a pesticide registration or to change the classification or hold a hearing on a pesticide. Recently, EPA and USDA signed a memorandum of understanding to establish an administrative mechanism for gathering and assessing information for

benefit/risk assessments whenever EPA finds that a pesticide meets or exceeds its criteria for unreasonable adverse effects to humans or to the environment. If this interagency relationship were extended to other areas, EPA would have better access to the extensive resources of USDA in the area of pest management. (See Chapter 3.)

- The cooperative action undertaken by EPA and USDA on benefit/risk assessments should be broadened so that EPA has ready and regular access to the extensive data resources of USDA on all aspects of pest management. For example, EPA should work with USDA to develop and conduct a survey, preferably on an annual basis, of the nation's use of pesticides.

Coordination of Monitoring Data

Environmental monitoring might be an important source of data for EPA decision making on pesticides. This monitoring could provide continuous, long-term information on the residues of pesticides and the effects of pesticides in air, soil, water, plants, and in humans and other nontarget species. FIFRA, as amended, assigns to EPA the responsibility for implementation of a National Pesticide Monitoring Plan. Essentially, this gives statutory authority to the National Pesticide Monitoring Program (NPMP), which began some years ago as a cooperative effort by several federal agencies. The effectiveness of the NPMP has been limited, however, by a lack of coordination among the federal agencies and a lack of operational continuity in the program. (See Chapter 2.)

- EPA should accept and act upon its statutory responsibility for the implementation of a National Pesticide Monitoring Plan by determining the data that are needed for the regulation of pesticides and by exerting leadership among the federal agencies with monitoring programs to assure that the NPMP adequately addresses these needs.

Regulatory Aspects

Consideration of Benefits

At present the EPA regulations on pesticides do not require the consideration of benefits as part of the EPA Administrator's decision to issue a notice of intent to deny or to cancel a registration. The disadvantage of focusing almost exclusively on risks in the early stages of decision making is that pesticide uses which are important to the agricultural economy, to human health, and to protect forests and buildings are not adequately studied or considered in initial decisions by the Agency. (See Chapter 2.)

- EPA regulations[1] should require, and not simply permit, the consideration of benefits in determinations of whether to issue a notice of intent to deny or to cancel a registration. This would conform with Section 2 [bb][2] of FIFRA, as amended.

Evaluation by Cancer Experts

The controversy about oncogenesis and mutagenesis in the regulation of pesticides will continue unabated until improved methods are available for determinations of carcinogenic activity and until scientists can agree on procedures to be used in assessing risks to humans and to the environment that may result from the use of pesticide chemicals. EPA must continue to meet its regulatory responsibilities, however, and should make use of the most authoritative scientific information that is now available to evaluate the carcinogenic potential of pesticides. (See Chapter 2.)

- The carcinogenic potential of any pesticide that exceeds EPA criteria for chronic toxicity (oncogenesis) should be evaluated by cancer experts. Initially, the EPA Carcinogen Assessment Group should make this evaluation, and its conclusions should be reviewed by other cancer specialists.

Restricted-Use Pesticides

If EPA does not meet the Congressional deadline of October 21, 1977 for the reregistration and classification of pesticides, this will severely undermine the landmark decision of Congress to permit

the use of some of the more toxic pesticides if they are classified for restricted use and are applied by trained and certified personnel so that these pesticides will be used safely. In order for this significant feature of FIFRA, as amended, to be implemented, the Committee on Pesticide Decision Making believes that EPA should give priority to the classification of pesticides in the restricted-use category. (See Chapter 2.)

- OPP should identify all pesticides that are likely to be placed in a restricted-use category and give them priority in the registration and reregistration process.

Minor-Use Pesticides

A special problem exists in the registration of pesticides for minor uses. These uses may involve major pests on minor crops or minor pests on major crops, but the total volume that is used of these pesticides is relatively small. The producers of these pesticides are reluctant to seek registration for minor uses because the market potential is not great enough to justify the costs of developing data that are required for registration. The fruit and vegetable and other crops on which these pesticides are used, however, make up a significant part of our diet even though they are grown in relatively small quantities. Pesticides also have minor uses in public health, structural, institutional, vertebrate, aquatic, ornamental, and veterinary pest control programs. The Committee on Pesticide Decision Making believes that EPA should explore the possibility of grouping pests and grouping crops so that producers of pesticides that are registered for use on similar pests and similar crops will not be forced to supply data which in many respects could be considered duplicative. (See Chapter 2.)

- EPA should investigate the scientific and regulatory feasibility of adopting the concept of grouping similar pests and similar crops when the data on these pests and crops are related and demonstrate the safety and efficacy of the pesticides.

Although some relief from the problems involving the minor uses of pesticides may be obtained through measures of this kind, the Committee concluded that these problems also require changes in FIFRA, as

amended, so that there is an improved statutory basis for dealing with pesticides that have minor uses. The following wording has the effect of permitting the use of a pesticide against a pest that is not specified on the pesticide label as long as the application is made to a crop or site that the label does specify. The Committee recommends that this wording be part of the changes that Congress is now considering in FIFRA, as amended:

- EPA should define the phrase, "it shall be unlawful...to use any registered pesticide in a manner inconsistent with its labeling," as follows:

  --application to a crop, animal, or site not included in the labeling claims, or

  --application of an amount of active ingredient, product per unit area, or space exceeding those on the labeling, or

  --failure to follow restrictions or limitations on the labeling.

Coordination of Research

The need to coordinate environmental research to prevent duplication and to enable EPA to get maximum benefits from the limited funding available for this purpose is one of the greatest problems facing the Agency. (See Chapter 2.)

- EPA should clear all contracts and grants for research on pesticides through its Office of Research and Development (ORD) to gain better coordination and centralized technical review of the research.

Although this clearance procedure might present some problems for the administrative and technical personnel in the Office of Pesticide Programs, these problems are likely to be outweighed by the benefits to be gained in time, research costs, and the coordination of information.

Improving the Status of Scientists

The role of scientific data, and of scientists to evaluate these data, is central to regulatory decision

making on pesticides. It was evident during the course of this study that EPA relies heavily upon the information and knowledge of its scientists and technicians in determining whether the use of a particular pesticide is safe or if it appears to meet or exceed the Agency's criteria of risk to humans or the environment. In its examination of the distribution of personnel in the Office of Pesticide Programs, the Committee concluded, however, that there are too few top-level positions for scientists in the OPP divisions. (See Chapter 4).

- Each major OPP division should add at least one senior scientist to its staff; additional scientists also are needed to increase OPP effectiveness in several occupational categories, including toxicology, pathology, and the mathematical, statistical, environmental, agricultural, social, and computer sciences.

OPP also should make it possible for its scientists to maintain good communications with their peers outside the Agency so that they can keep up with developments in their specialized fields.

- EPA should expand the opportunities for its scientists to communicate with their peers in the greater scientific community by encouraging participation in scientific meetings and by increasing the opportunities for an exchange of scientists between EPA and universities and other institutions and agencies.

OTHER RECOMMENDATIONS

The Committee made a number of specialized recommendations that are included within relevant sections of this report. These recommendations relate to the publication of research studies on pesticides; the publication of data from monitoring studies on pesticide residues; the communication of information on EPA regulatory actions on pesticides to state agencies and other groups; the improvement of internal communications within EPA, including the coordination of scientific effort in the EPA Office of Pesticide Programs; and the need for international cooperation in the development of effective pest management and pesticide regulation programs. Other recommendations are concerned with procedures that deal with the

registration of pesticides classified for restricted use, the disposal of cancelled pesticides, and with the need for expeditious response by EPA to requests for experimental use permits and for exemptions from regular EPA procedures when there are pest outbreaks of an emergency nature.

NOTES

1 40 CFR 162.11 [a] [5] [iii]: "At the time that a registrant or applicant submits evidence in rebuttal of the presumption, he may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use. In determining whether to issue a notice pursuant to section 3(c) (6) or section 6(b) (1) or to issue notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, in accordance with paragraph (a) (5) (ii) of this Sec. 162.11, the Administrator may, in his discretion, take into account staff recommendations resulting from preliminary analysis, if any, concerning the balancing of risks against benefits. Any such preliminary analysis shall be completed within one hundred and fifty (150) days from the date notice is sent to the applicant or registrant in accordance with subparagraph (1) of this Sec. 162.11(a). If based on such analysis the staff recommendation is that benefits appear to outweigh risks, the Administrator may, in his discretion, issue notice of intent to hold a hearing to determine whether the registration should be cancelled or denied rather than a notice pursuant to section 6(b) (1) or section 3(c) (6) of the Act. If the recommendation is that benefits do not appear to outweigh the risks, the Administrator shall issue a notice pursuant to section 3(c) (6) or section 6(b) (1) of the Act, as appropriate." (See Chapter 2 for a discussion of this regulation.)

2 Section 2 [bb] of FIFRA, as amended: "UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT. -- The term 'unreasonable adverse effects on the environment' means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." (See Chapter 2 for discussion.)

CHAPTER 1

PESTICIDE REGULATION

INTRODUCTION

Pesticide regulation in the United States has evolved from narrow objectives in which the major concern was to protect the user of pesticides to a comprehensive concern for the short- and long-term effects on human beings and on the environment of the use of pesticides. The greatest changes were made in 1972, when the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (FIFRA) was amended by FEPCA, the Federal Environmental Pesticide Control Act (PL 92-516). Further amendments were made to FIFRA in 1975 (PL 94-140). These changes in the law transformed FIFRA from a registration statute that afforded some degree of protection to the users of pesticides to a regulatory statute under which EPA has broad and flexible authority extending beyond the registration of pesticides to the control of their use.

Additional EPA legislative authority for pesticide regulation is provided by Sections 408 (21 USC 346a) and 409 (21 USC 348) of the Federal Food, Drug, and Cosmetic Act, which relate to the control of pesticide residues in food and feed.

STATEMENT OF THE PROBLEM

When EPA evaluates a pesticide and decides whether to permit its registration or reregistration or to ban or restrict its use, the Agency must determine that a pesticide is efficacious for the control of target species and that it will not result in unreasonable adverse effects on human beings or the environment. The first determination can be made on the basis of scientific procedures alone. The second determination is also based on scientific data insofar as it is possible to predict quantitatively the risks resulting from a particular use of a pesticide; however, the

ultimate decision of whether this use will pose an unreasonable risk to humans or to the environment is a judgmental decision involving determinations of what constitutes an unreasonable risk and, often, evidence that is suggestive rather than absolute. EPA's administrative decisions are further complicated in this area by the fact that the Agency is required by law to balance such risks against the benefits to be derived from the use of a pesticide.

The complex issues relating to benefits and risks are at the heart of the controversy that has surrounded EPA since the Agency banned most uses of DDT. For example: if a particular use of a pesticide will save farmers several million dollars that they might otherwise incur in crop losses, if it will help to provide additional food for thousands of people who need it, and if it will help to keep the price of certain foods within reach of the average person, but at the same time it may cause some additional deaths from cancer, should EPA permit the product to be registered and sold? If a pesticide could save a thousand lives from a vector-borne disease, such as malaria, but may also cause ten deaths from cancer, should EPA permit its use? And is it possible to establish scientific relationships among such data? What scientific information is available on the oncogenicity of a pesticide product; what is the scientific basis for EPA conclusions on potential oncogenicity; and how and to what extent does EPA employ scientific findings in its decision making on pesticides?

The principle that a risk/benefit decision ultimately is a policy or value judgment is generally accepted. To be valid in EPA decision making, these value choices must flow from a scientific foundation that is carefully laid. This is particularly important because often it is scientifically impossible or economically infeasible to acquire information on a pesticide before it has wide application; out of necessity, therefore, value judgments based on scientific information must be substituted for conclusions that can be supported by evidence. Thus, scientific input into the EPA decision-making process should be maximized, and the issue becomes how this can best be done. But this issue, which is a key to the sound resolution of problems that are inherent in the regulation of pesticides, tends to be ignored in the bitter controversies that have surrounded past decisions of EPA. Users of pesticides fear that they will be regulated to the point where pests cannot be

effectively controlled, with concomitant losses of food, while opponents of the use of pesticides fear that people are being poisoned and that irreversible damage is being done to the environment.

The Committee on Pesticide Decision Making is concerned about the controversy over pesticides and the fact that opinions have become polarized over this issue. Furthermore, many of the arguments put forward in the controversy have failed to address the question of how problems in the regulation of pesticides can best be resolved.

Clearly, risk/benefit analyses must be used in decision making on pesticide use and control. It is not possible to state definitely the weight that should be given to scientific information in these analyses because of the many uncertainties and unknowns in the factors involved. At all stages of the decision-making process, however, EPA should have access to the best available scientific information and should obtain adequate peer review of the scientific information it uses in making decisions. EPA also must aggressively sponsor and participate in research so that society, whose exposure to pesticides usually is involuntary, can make decisions about acceptable risks on the basis of improved scientific knowledge, especially in relation to any carcinogenesis that may be caused by the use of pesticide chemicals. These are among the central issues discussed in this report, which recognizes that the complex issues involved in the nation's effort to regulate pesticides can and must be resolved.

EPA PESTICIDE ACTIVITIES

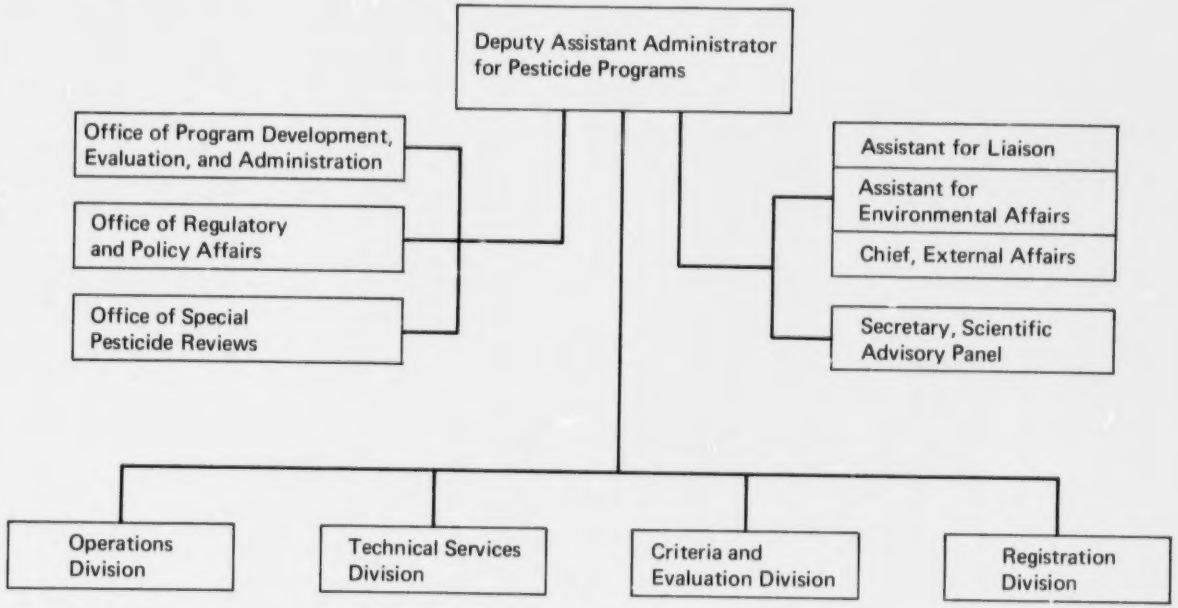
The Environmental Protection Agency became operative on December 2, 1970, after being established by Reorganization Plan No. 3. The new Agency inherited several ongoing programs, including those dealing with pesticide registration from the U.S. Department of Agriculture (USDA) and those dealing with the setting of tolerances from the U.S. Department of Health, Education, and Welfare (HEW). Later, EPA received expanded directives from the Congress through the 1972 and 1975 Amendments to FIFRA (Public Laws 92-516 and 94-140). Although the Agency shares some pesticide enforcement and related responsibilities with HEW, USDA, the Occupational Safety and Health Administration, and the U.S. Department of the

Interior, under federal law the major regulatory functions for pesticides now rest with EPA.

Office of Pesticide Programs

The EPA component with decision-making functions in the regulation of pesticides is the Office of Pesticide Programs (OPP), one of five units that was under the EPA Assistant Administrator for Water and Hazardous Materials. The line of administrative responsibility for the regulation of pesticides now runs from the Deputy Assistant Administrator of OPP to the Assistant Administrator for Toxic Substances and Pesticides, and then ascends to the EPA Deputy Administrator and to the EPA Administrator. Other branches of EPA that assist OPP in carrying out some of its responsibilities are the Office of the Assistant Administrator for Enforcement, the Office of the Assistant Administrator for Research and Development, the Office of General Counsel, and, on occasion, the Office of Solid Waste Management Programs.

The OPP has eleven functional components (see Figure 1.1). OPP responsibilities include the development of strategic plans for the regulation of pesticides by EPA and by other federal agencies, or by state, local, and private sectors; establishment of guidelines and standards for the examination of pesticide products; the setting of tolerance levels for pesticide residues occurring in or on food; development of monitoring requirements for the pesticide program; review of pesticide formulations and of relevant data on both the efficacy of a pesticide and any hazards to human beings or to the environment that may result from its use; establishment of restrictions governing the sale and use of pesticides; registration, reregistration, or denial or cancellation of pesticide registrations; monitoring of residue levels of pesticides in food, humans, nontarget species, and the environment; investigation of pesticide incidents and accidents; preparation of model legislation for use by states and other levels of government in developing more effective programs to regulate pesticides; provision of program policy direction for technical and manpower training activities in the area of pesticides; and identification of research needs for the regulation of pesticides.


Deputy Assistant Administrator for Pesticide Programs
Office of Program Development, Evaluation, and Administration
Office of Regulatory and Policy Affairs
Office of Special Pesticide Reviews
Assistant for Liaison
Assistant for Environmental Affairs
Chief, External Affairs
Secretary, Scientific Advisory Panel
Operations Division
Technical Services Division
Criteria and Evaluation Division
Registration Division

SOURCE: U.S. EPA.

FIGURE 1.1 Organization of EPA Office of Pesticide Programs.

OPP Divisions and Offices

The OPP units with the principal administrative responsibilities for the day-to-day operation of the EPA pesticide program are the Registration Division, Criteria and Evaluation Division, Technical Services Division, Operations Division, and the Office of Special Pesticide Reviews.

The Registration Division has the primary role in the regulation of pesticides. It is responsible for the registration of pesticides; the classification of pesticides for either general or restricted use; establishment of tolerance levels for pesticide residues in food and feed; and technical support for EPA enforcement actions.

The Office of Special Pesticide Reviews (OSPR) was set up within OPP late in 1975 to review pesticides for which there is a Rebuttable Presumption Against Registration (RPAR). A rebuttable presumption occurs when a pesticide, its metabolites, or its degradation products meet or exceed the criteria that EPA has established to determine when a pesticide has unreasonable adverse effects on humans or the environment. This office performs in-depth analyses of the risks and benefits of pesticides that are suspected of causing unreasonable adverse effects.

The OPP Criteria and Evaluation Division establishes the standards and criteria used by OPP to evaluate the safety and efficacy of pesticides in the registration and reregistration process and to set tolerances for residues of pesticides in food and feed; reviews registered pesticide chemicals and assesses the environmental, human safety, and risk/benefit aspects of their continued use; provides technical support in the conduct of regulatory actions and statutory appeals; and develops guidelines, standards, criteria, and monitoring requirements for the regulation of pesticides.

The Technical Services Division operates computer data systems and provides computer programming support to meet OPP operating needs; provides information to other federal and state agencies on the registered uses of pesticides and on the tolerances for pesticide residues in food and feed; collects data from pesticide monitoring programs; produces scientific publications and provides specialized library and reference services; supervises OPP laboratory operations; and

develops analytical reference standards to support regulatory activities relating to pesticides.

The Operations Division provides program policy direction for technical assistance and training programs relating to pesticides; develops model legislation on pesticides for use by states and helps states to develop and improve their pesticide programs; participates in federal interagency activities on pesticides; and conducts investigations of pesticide incidents and accidents.

CHAPTER 2

THE ROLE OF DATA IN EPA DECISIONS ON PESTICIDES

Registration is the key procedure in the regulation of pesticides in the United States. In order to be marketed, a new pesticide must be registered by EPA for a restricted or a general use under the provisions of FIFRA, as amended. The 33,000 pesticides that were registered by USDA before EPA was set up in 1970, and by EPA prior to the amendments to FIFRA in 1972 and the establishment of new registration regulations in 1975, must be reregistered. This legislation also requires that every five years a registered pesticide must undergo an EPA review similar to that for new registrations. Thus, in time, all pesticides sold and used in the United States must have met the requirements of FIFRA, as amended, and be effective in their stated use; they must not have unreasonable adverse effects on human beings or the environment; and they must be registered by EPA.

In determining whether to register a pesticide use or to cancel a use already registered, EPA depends upon the development, evaluation, and use of scientific data. This chapter is concerned with the vital role of data in EPA decisions and evaluates how the Agency gathers and uses data in a number of procedures involved in pesticide regulation.

REGISTRATION AND REREGISTRATION

Under FIFRA, as amended, data supporting the registration of pesticides are generated by interested parties. These data usually are developed by or for chemical manufacturing firms and are then submitted to EPA with applications for registration. In compliance with Section 3(c)(2) of FIFRA, as amended, the Office of Pesticide Programs is developing guidelines, which describe the types of data needed for registration and reregistration, and appendices to these guidelines,

which contain examples of test procedures that are acceptable to EPA. The guidelines were published as proposed informal rules in the Federal Register in June 1975 (U.S. EPA 1975).

The range of variables in the proposed guidelines is expected to apply to most pesticide registrations. In publishing these proposals, however, EPA stated:

> Neither the Guidelines themselves nor the Appendices are static documents. They will be expanded and revised periodically to reflect new scientific knowledge, new trends in pesticide development, and new Agency policies...Any applicant who considers that certain provisions of the Guidelines may not be appropriate for a particular pesticide should submit a written statement of his position, and consult with the Office to determine what data are necessary in his particular case.

Proposed registrations of pesticides are routed to an evaluation team in the OPP Registration Division. This team is chiefly interested in the chemical aspects of a pesticide: the common name, if any; the chemical structure; an assay of its active ingredients and principal impurities and the methods used for such determinations; the method of manufacture; the physical and chemical properties; and other pertinent chemical information. If this review discloses deficiencies in the information that has been submitted for registration, the applicant is notified and asked to provide whatever additional information is needed.

Next, the application goes to a product manager team in the Registration Division. The functions of these teams were outlined in EPA regulations (40 CFR 162.46):

> ...each product is assigned to a single team headed by a Product Manager...Assignment is generally by active ingredient and use: for example, one Product Manager handles all quaternary ammonium disinfectants; another, all chlorinated hydrocarbons; and a third, most fumigant-type products. With minor exceptions, the team to which the product is assigned handles all registration or other actions relating to the product, including registration, amendments to registration, resubmissions, renewals, petitions for

tolerance, and, if necessary, cancellations or suspensions. Exceptions include enforcement case reviews, distributor brand applications, and experimental use permits; even in these cases, the Product Manager is kept informed of actions affecting his product.

Depending on the background and experience of individual team members, the review by the product manager teams includes a study of the efficacy, phytotoxicity, human safety, and some ecological effects of the pesticide. The amount of review depends in part on the quantity and quality of the data presented in support of the registration, on the magnitude of changes proposed in the pattern of use, and on the formulation of the pesticide product and the presence or absence of any known toxic agents. In doing these reviews, the product manager teams rely heavily upon consultation with their peers, comparison of the data that have been submitted with data in EPA files for previously registered pesticides that are identical or similar, and upon their own judgment.

If the proposed registration survives this review, the application proceeds on its way to registration. But if the review indicates that the pesticide may have unreasonable adverse effects on humans or on the environment, as defined by EPA criteria, the product is then referred to the OPP Office of Special Pesticide Reviews (OSPR) who may in turn issue a Rebuttable Presumption Against Registration (RPAR). The applicant must then rebut the OPP findings of unreasonable adverse effects in order to get the pesticide registered or reregistered. The criteria that trigger the RPAR process and the process itself are described in the Cancellation/Suspension section of this chapter.

Congress has directed EPA to review, by October 21, 1977, all pesticides that were registered before the amendments to FIFRA were enacted and to subject these pesticides to a reregistration process. The purpose for this review is to place all pesticides under the standards for safety of the FIFRA amendments, which are more stringent than the standards that were in existence under earlier legislation. This review of older pesticide products is in addition to EPA's ongoing responsibilities for processing new applications for pesticide registration and for the review of more than 4,000 existing tolerances for pesticide residues in food or feed (see the section on Tolerances in this chapter).

EPA has had many problems in implementing these Congressional mandates on pesticides. Much of the difficulty centers on "data gaps" that became apparent when EPA began reviewing pesticides for reregistration. In many cases, the available data on older pesticide products were found to be faulty and incomplete both in terms of current scientific standards and in terms of the requirements of FIFRA, as amended, that a pesticide should not cause any unreasonable adverse effects to humans or to the environment.

EPA has more than one million pieces of data, going back to 1947, in its files. These are still being cataloged for reference purposes and, until a catalog is available, it is virtually impossible for the Agency to verify a reference for a piece of data and to validate these data according to today's standards. The problems involved in this undertaking also are great because it is now necessary for the Agency to assess the oncogenic effects of a pesticide, a major criterion for the determination of unreasonable adverse effects under the FIFRA amendments. Oncogenic potential, and particularly the potential for causing cancer, is difficult to establish in terms of absolute scientific proof. Generally, oncogenesis is determined on the basis of laboratory tests and on an extrapolation of the results to possible effects in humans. Much controversy surrounds this entire issue (see the Cancellation/Suspension section of this chapter for a more complete discussion of the problem).

In May 1976, EPA attempted to expedite its reregistration process by creating a new category of conditional registration for older products that lacked necessary data. This type of registration would have permitted pesticides to be sold while laboratory testing was undertaken to provide the necessary additional data. At the same time, EPA would require that new products coming before it for registration for the first time would need to satisfy all the data required by FIFRA, as amended. There were widespread objections to the EPA plan for conditionally reregistering pesticides on the grounds that it would continue the double standard for products being registered and those registered earlier under the old regulations of FIFRA.

EPA halted its registration and reregistration of pesticides in August 1976, and it is difficult to determine how long this situation will continue to exist. One prediction was made by Dr. Andrew Breidenbach, then Assistant Administrator of EPA for

Water and Hazardous Materials, who testified before the Senate Committee on Agriculture and Forestry in the spring of 1977 that, "Registration including data validation for all products will take, at the current resource level, 10-15 years."

CLASSIFICATION

FIFRA, as amended, requires that all pesticides be classified for either general or restricted use; this occurs during registration or reregistration. An EPA spokesman (Quarles 1975) said classification is:

> ...one of the most significant innovations in the history of pesticide legislation...restricting the use of the more toxic pesticides to persons of demonstrated competence enables us to allow the continued use of chemicals whose adverse effects under general use conditions could have led to their cancellation under the 1947 FIFRA [the legislation before amendment in 1972 and 1975].

Despite continued delays in the EPA reregistration and classification of pesticides, the certification of applicators for restricted-use pesticides is proceeding at a reasonable pace. By April 1, 1977, there were 160,710 commercial applicators and 624,415 private applicators who had been trained for certification under plans approved by EPA (personal communication from L.C. Gibbs, Program Leader for Pesticide Chemicals, Extension Service, USDA).

If EPA does not meet the Congressional deadline of October 21, 1977 for the reregistration and classification of pesticides, this will severely undermine the landmark decision of Congress to permit the use of some of the more toxic pesticides if they are classified for restricted use and are applied by trained and certified personnel so that they will be used safely. The publication in December 1976 of a list of candidates for the restricted-use category of pesticides has, to some degree, eased the problems faced by states in completing certification programs for pesticide applicators. However, this list of pesticide candidates does not represent a full review of all pesticide products and does not, therefore, satisfy the requirement of Congress that EPA classify all pesticide uses by the October 1977 deadline. In order for this significant feature of FIFRA, as

amended, to be implemented, the Committee on Pesticide Decision Making believes that EPA should give priority to the classification of pesticides in the restricted-use category.

Recommendation

- OPP should identify all pesticides that are likely to be placed in a restricted-use category and give them priority in the registration and reregistration process.

CANCELLATION/SUSPENSION

FIFRA, as amended, provides that the registration of a pesticide will be automatically cancelled five years after its initial registration unless the registrant requests an extension. This legislation also gives the Administrator the authority to cancel the registration of a pesticide or to change its classification when there is information indicating that the product does not comply with provisions of the Act. Before making a decision of this kind, the Administrator may hold a hearing to determine whether action should be taken. A hearing must be held, however, when an Agency decision to cancel or change the classification of a pesticide is contested by the registrant. When a notice is issued of the Agency's intent to take such action, the Administrator may suspend the use of the pesticide if it poses an imminent hazard to human beings or the environment.

Rebuttable Presumption Against Registration

In 1975, EPA issued regulations containing the criteria and procedures by which pesticides are screened for possible cancellation and suspension. These criteria are an administrative determination of what constitutes "unreasonable adverse effects" under FIFRA, as amended, and they provide the regulatory framework for EPA's Rebuttable Presumption Against Registration (RPAR) process. A rebuttable presumption exists when a pesticide's ingredients, metabolites, or degradation products meet or exceed these stated criteria of risk (40 CFR 162.11):

- when there is a hazard of acute toxicity in humans, domestic animals or wildlife (measured by formulas for lethal doses);

- when there is a hazard of chronic toxicity--oncogenic effects (i.e., any tumor) are induced in humans or in experimental animals as a result of oral, inhalation, or dermal exposure; mutagenic effects are induced, as determined by multitest evidence; any other chronic effect is produced in test animals; or it is expected that the pesticide will significantly reduce nontarget organisms or be fatal to endangered species; or

- when there is no antidote or other emergency treatment for toxic effects in humans from a single exposure to the pesticide.

When the RPAR process has been set in motion, the registrant or the reregistrant of the pesticide has the burden of proving that the anticipated exposure of persons who use the pesticide or of nontarget organisms is unlikely to result in any significant adverse effects of an acute nature. Registrants and reregistrants must also offer proof that, when the pesticide is used according to commonly recognized practices and with proposed restrictions on its use, it will not concentrate, persist, or accumulate to levels in humans or in the environment which will result in any significant adverse effects of a chronic nature. In addition, the applicant may submit evidence that the economic, social, and environmental benefits to be derived from the use of the pesticide outweigh the risks of its use. Furthermore, in making a decision to cancel or change the classification of a pesticide, the Administrator must take into account the impact of this action on the agricultural economy and on retail food prices.

The RPAR process is a somewhat involved procedure which permits a detailed examination of the effects of using pesticide chemicals that appear to meet or exceed EPA criteria for "unreasonable adverse effects." However, it would be a misuse of this procedure, which is usually lengthy, to employ it for pesticides whose proposed uses are such that there would not be unreasonable adverse effects if their registration were restricted to certain uses.

Recommendation

- The OPP Registration Division should resolve registration and reregistration problems whenever possible before resorting to the RPAR process if a pesticide will have a

restricted use or when its pattern of use will not create unreasonable adverse effects.

EPA Criteria for Carcinogenesis

The District of Columbia Circuit Court of Appeals has had a major role in shaping EPA's interpretation of its legislative mandate to protect human beings and the environment from unreasonable adverse effects resulting from the use of pesticides. Since 1970, this court has rendered a series of far-reaching decisions on the regulation of pesticides in which EPA cancellation and suspension orders were reviewed. In effect, the court told the Agency to develop a general policy for interpreting data on risks of cancer resulting from the use of pesticides. In 1974, the Agency began to develop principles on which to base its criteria for the interpretation of such data, and the court has since held that these principles are part of the Agency's scientific expertise. Thus, the Agency may use these principles to interpret data submitted for use in the RPAR process.

A major controversy over the EPA regulations for the RPAR process concerns questions about evidence that a pesticide may have oncogenic effects. Should the Agency deny or cancel a registration, for example, because extrapolations from data on mice and other rodents show carcinogenic potential? Should the Agency take into account scientific judgments that, even though there is evidence of a risk of oncogenesis, the particular use sought for a pesticide would not pose an unreasonable adverse effect to humans or to the environment? Given the judgment that "there is no battery of tests, however elaborate, which can prove beyond challenge the complete safety of a chemical" (NRC 1975c), it is difficult for an applicant or registrant to rebut a presumption of oncogenesis, or more specifically, of carcinogenesis, because methods are not available to quantify the risk. It should be noted, however, that EPA has not always cancelled all uses of a pesticide solely on the basis of data showing a possible risk of oncogenesis. In a few cases, specific uses of a pesticide have been judged as not causing unreasonable adverse effects because effective alternatives were generally not available, the risk of exposure arising from that specific use was minimal, and the benefits of the use outweighed the risk.

EPA has organized a Carcinogen Assessment Group (CAG), made up of senior scientists from the Agency and

experts on cancer from major medical and research centers, to advise the EPA Administrator on the risks to health associated with suspected carcinogens. The CAG meets in response to problems of carcinogenicity that arise in connection with any of the Agency's regulatory programs.

Recommendation

- The carcinogenic potential of any pesticide that exceeds EPA criteria for chronic toxicity (oncogenesis) should be evaluated by cancer experts. Initially, the EPA Cancer Assessment Group should make this evaluation, and its conclusions should be reviewed by other cancer specialists.

Research Needed On Carcinogenesis

Adequate epidemiological data on cancer victims to detect possible relationships to pesticide use are not available. Moreover, no toxicological methodology has been developed which will assure that a pesticide that induces tumors will--or will not--necessarily induce cancer. While the relative carcinogenic potential of a pesticide can be assumed with reasonable accuracy from the induction of preneoplastic lesions and neoplastic growth in laboratory mammals, this method of assessing cancer risks poses many difficulties. Among these difficulties are problems in estimating risks to human populations with data derived in tests on rodents and other small mammals, in extrapolating from experiments in which massive doses were administered over short periods of time to form conclusions about the effects of small doses that are received over long periods of time, and in identifying a threshold for the physiological action of a chemical.

More recently, data and information have been acquired on the use of bacterial, cell culture, tissue culture, and other *in vitro* techniques. These techniques have serious drawbacks in determining the carcinogenic potential of a pesticide. For example, the *in vitro* results, obtained in an artificial setting, may bear no direct relationship to the *in vivo* effects of pesticides in human beings. Despite these limitations, *in vitro* and *in vivo* tests offer the best available mechanism of prescreening for prediction of carcinogenic potential.

The problem of estimating cancer risks to humans due to exposures to chemicals is not unique to EPA/OPP, and it goes far beyond the regulation of pesticides. There are fundamental similarities in the problems encountered by EPA and other federal regulatory agencies in estimating the risks to humans from exposures to vinyl chloride, asbestos, DDT, diethylstilbestrol residues in beef, Red Dyes #2 and #40, benzene, nitrosamines, aflatoxin, chloroform, and other chemicals.

The controversy about oncogenesis and mutagenesis in the regulation of pesticides will continue unabated until improved methods are available for determinations of carcinogenic activity and until scientists agree on procedures to be used to assess risks to humans and to the environment resulting from the use of chemicals. Research supported by FDA and EPA at the National Center for Toxicological Research is directed at some of the data requirements for the regulation of pesticide chemicals. It is unlikely, however, that the controversy over oncogenesis can be resolved without a more extensive national research effort to obtain the information needed by federal regulatory agencies in the evaluation of data on carcinogenicity. Until this effort is made, EPA should fund research to develop relative determinations of carcinogenic risk to humans and the environment as a result of pesticide use.

Recommendation

- EPA should sponsor research to obtain broad determinations of the levels of human exposure to carcinogens in the environment. In addition, a multiagency effort should be undertaken to develop national criteria for interpreting data on carcinogens, and for assessing the carcinogenic risks of human exposures to pesticides.

In the proposed multiagency research effort, the research should develop data in these important areas:

- the biological significance of oncogenic responses in various test systems as a basis for predicting carcinogenic risks to humans;

- the relationships between dose and response in appropriate in vivo systems with correlations over a wide range of doses and, preferentially, of

relationships that fall within the relevant ranges of human exposure;

- critical evaluation of mathematical probability models for predicting estimates of carcinogenic risk when extrapolations are made from high test doses of chemicals given over a short span of time to low human exposures received over a long span of time;

- the quantitative relationships between *in vitro* tests, such as the Ames test (Ames et al. 1973, McCann et al. 1975), and *in vivo* bioassays, and the relevance of these relationships in establishing human risks of cancer;

- the existence, distribution, and estimated margin of safety of susceptible population groups; and

- the additive effects of various carcinogens and the effects of cocarcinogens, promoters, and modifiers on the total carcinogenic insult to humans.

Procedural Aspects of the RPAR Process

Soon after the administration of FIFRA was transferred from USDA to EPA in 1970, and before the RPAR process was set up, the OPP Criteria and Evaluation Division began compiling a list of pesticides suspected of being hazardous to humans or the environment. Initially, these suspect chemicals were selected on the basis of information in various scientific reports, including the Mrak report (U.S. DHEW 1969). The information was used primarily by the EPA Office of General Counsel in the development of strategy for cancellation proceedings against DDT, aldrin, dieldrin, chlordane, heptachlor, and 2,4,5-T. With implementation of the RPAR process, which was begun in 1975, and the assignment of its administration to a newly-formed Office of Special Pesticide Reviews (OSPR) in the Office of Pesticide Programs, the Suspect Chemical Review Program was terminated and the pesticides on its list were placed on a list of possible RPAR candidates. Additional RPAR candidates now come from reregistration reviews, applications for new pesticide registrations, and from public complaints and other outside sources.

When the OPP Registration Division determines, in its review of a pesticide for registration or reregistration, that the product meets or exceeds any

of the EPA criteria of risk to humans or the environment, and that a rebuttable presumption against its registration exists, the pesticide enters the RPAR process and comes under the purview of the OPP Office of Special Pesticide Reviews. An advantage of the RPAR process is that it allows EPA to gather extensive scientific information on the effects of a chemical before the Agency determines whether prolonged, courtroom-type hearings are necessary. The following steps are taken in the RPAR process:

1. The applicant is initially given 45 days to submit evidence in rebuttal of the "presumption of risk" (this period may be extended for an additional 60 days).

2. At the end of this period, EPA determines whether the allegations of risk have been rebutted successfully.

3. If the rebuttal was successful, EPA permits registration or reregistration of the pesticide; if the applicant has not made a successful rebuttal, the Administrator issues a notice to cancel, deny registration, or change the classification of the pesticide, or a notice of intent to hold a hearing.

When OSPR was established in OPP in 1975, it was to be a temporary organizational unit that was specifically set up to handle the RPAR workload. Because the handling of RPAR cases for registration and reregistration was expected to require a concerted and continuous effort for the next two years, it was not considered feasible to add this task to the ongoing work being done by the existing divisions in OPP.

OSPR was established on the project manager concept (not to be confused with the product manager system in the OPP Registration Division, which was mentioned earlier in the Registration and Reregistration section of this chapter). Originally, five to ten OPP staff members were to be assigned, as needed, to OSPR to work as project managers. Each one was to be responsible for managing specific pesticide cases in the RPAR process from beginning to end, i.e., from the determination that a rebuttable presumption appears to exist through any hearings that might be held on a pesticide. Since that time, OSPR has achieved permanent status and consideration is now being given to making it a division, rather than an office, within OPP. When OSPR is fully staffed, it is expected to consist of a director and a deputy director, branch

chiefs (each one responsible for at least five project managers), and clerical support. The fact that OSPR has now been set up as a permanent unit composed of at least 20 project managers suggests that a minimum of 20 pesticides will be under RPAR review at all times. This is in contrast to the original concept of a temporary organization made up of five to ten OPP staff members that were to be assigned as necessary to work in the unit as project managers.

A Pesticide Chemical Review Committee (PCRC) has been established to provide policy review within EPA for the OSPR operation. PCRC is chaired by the Director of OSPR and is composed of representatives of other areas in EPA; i.e., the Office of General Counsel, the Carcinogen Assessment Group, the Office of Enforcement, the Office of Research and Development, the Office of Toxic Substances, and the Office of Planning and Management.

For each pesticide in the RPAR process assigned to a project manager, a working group is named and made up of people from the units represented on PCRC. Each working group member continues to serve in this role throughout the entire period that a compound is in the RPAR process. The working groups assist project managers in these functions:

- the preparation of all decision documents and related materials (PCRC reviews these documents);

- keeping PCRC members informed of the issues and progress of the RPAR process in each case;

- establishing contact with all available technical and scientific sources within and outside the Agency who may be called upon to assist or to contribute to the RPAR review; and

- working with the EPA Office of General Counsel, if hearings are held on a pesticide, in planning and preparing EPA's presentations and recommendations to the hearing officer.

PCRC and the working groups are made up of people who, for the most part, come from units other than OPP. These units are not directly involved with pesticides on a day-to-day basis. It is the opinion of this Committee that the RPAR process is an important step in the cancellation and suspension procedure and that the staff appointed to carry out this procedure should be composed of scientists and policymakers who are

knowledgeable about pesticides. If the OSPR function is to be successful, it must be flexible so that it can meet the variety of tasks which are required and it must represent the highest level of scientific expertise.

Extensive Analyses of Risks and Benefits

Information on the risks and benefits resulting from the use of a pesticide may be developed and analyzed by EPA during much of the decision-making process. These factors must be weighed and balanced in the RPAR process and must enter into Agency decisions to hold a hearing, or to deny, cancel, or reclassify a pesticide registration.

Furthermore, EPA is required by FIFRA, as amended, to take into account the impact of a proposed action against a pesticide on the production and prices of agricultural commodities, on other aspects of the agricultural economy, and on retail food prices. The Agency must notify the U.S. Department of Agriculture of an intended action of this kind and provide USDA with a copy of its analyses of the agricultural impact. The EPA Administrator must also submit a notice of intent to cancel or change the use of a pesticide to an independent Scientific Advisory Panel, whose members are chosen according to provisions of FIFRA, as amended. The panel comments on the impact that a proposed decision is likely to have on human health and the environment.

Depending upon the complexity of the issues, cancellation hearings may last for a year or more. During these hearings, the EPA Administrator may allow a pesticide to continue to be sold and used, or may suspend the sale and use of the pesticide if there is evidence that the pesticide poses an imminent hazard to human beings or the environment.

EPA Hearings on Pesticides

FIFRA, as amended, specifies that when a hearing is held by EPA, either on its own initiative or in response to the request of an applicant, it must be presided over by a hearing examiner. In most cases, this examiner has been an administrative law judge. The examiner, under the law, has the power to issue a subpoena to compel testimony or production of documents from any person.

Some scientists and other people concerned about the efficiency and equity of EPA decision making have pointed out the limitations of a trial-type hearing (NRC 1977a), which is the format used in hearings on pesticides. In these proceedings, the applicant and the Agency take adversary roles. The applicant submits information to support registration or reregistration; EPA submits information to support its contention that a pesticide meets or exceeds the Agency's criteria of risk to humans or the environment. This format can limit and distort the role of scientific information and judgment in decision making on pesticides. It is also time consuming and costly.

Although the statutory requirements for hearings on pesticides contain some specifications on how the hearings shall be held--that is, with a hearing examiner as presiding officer, and in accordance with certain provisions of the U.S. Code and guided by the principles of the Federal Rules of Civil Procedure--the Committee on Pesticide Decision Making believes that some modification in the format of the hearings should be made so that they are less adversary and more like the usual public hearing or rule-making procedure. (For a more complete discussion of the advantages and disadvantages of trial-type proceedings in EPA decision making, see Chapter 4 in NRC 1977a.) The recommended modification would better serve the interests of the Agency, the applicant, and society because, by lessening the adversary character of the hearings, it would open up the hearings to a full consideration of scientific information and judgment about the use of a pesticide. This should help to resolve issues that are often extremely complex and should permit the best possible evaluations of the quality of both positive and negative data, the expected exposures to a pesticide, the relative risks to various sectors of the population and to the environment, the oncogenic risks posed by a pesticide, and the trade-off between risks and benefits that must be considered in the final EPA decision.

Disposal of Cancelled Pesticides

The recent suspension of most uses of heptachlor and chlordane offers insight into one problem that may be created by a cancellation and suspension notice. On December 24, 1975, the EPA Administrator issued an order suspending further production of heptachlor and chlordane except for limited minor uses. However, the impact of the order was tempered by delaying until

August 1, 1976 the date that the prohibition on production became effective for the use of these compounds on corn pests. The Administrator also permitted the sale and use of existing stocks of the compounds if they had been manufactured before July 29, 1975.

The Environmental Defense Fund (EDF) charged that the EPA order did not offer adequate protection against hazards resulting from the use of heptachlor and chlordane, and the group sought an injunction against the continued production and use of the pesticides on corn pests. EDF also challenged the Administrator's decision to allow continued use of existing stocks on the basis that EPA should have provided for the retrieval and controlled disposal of these stocks.

Judge Leventhal of the U.S. Court of Appeals of the District of Columbia Circuit affirmed the Agency's suspension order, but noted that, "Although we have no doubt that the Administrator has the power under FIFRA to exempt from a suspension order the use of existing stocks ...the Administrator acted arbitrarily when he failed to even inquire into the amount of stocks left, and the problem of returning and disposing of them" (Bureau of National Affairs 1976).

Recommendation

- EPA should make a detailed review of potential problems involved in the safe disposal of a pesticide before it issues a cancellation order.

RISK/BENEFIT ASSESSMENT

Risk and Benefit Information Used by EPA

Amended FIFRA, the statutory basis for EPA's regulation of pesticides, specifically requires the Agency to consider the risks and benefits associated with pesticide regulatory activities. In its definition of "unreasonable adverse effects on the environment," the Act says this is "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" (PL 92-516, Sec. 2 [bb]). Consequently, these risks, costs, and benefits must be considered when EPA approves, denies, cancels, or restricts the use of a pesticide, and when it finds

that a pesticide poses an imminent hazard to human health or to the environment.

In the EPA regulations for amended FIFRA (40 CFR 162.11), the decision-making process which leads to the possible cancellation, denial, or change in the registration of a pesticide appears to be a two-step procedure. In the first step, EPA evaluates the health and environmental risks that may result from use of a pesticide on the basis of the Agency's criteria for toxicity or other risk. (The criteria, which are identified in the RPAR procedure, are discussed in the Cancellation/Suspension section of this chapter.) Use patterns, the potential number of toxic events, economic data, or data on benefits are not considered during the initial evaluation of a pesticide.

A second step in the EPA decision-making process occurs when, on the basis of the initial evaluation, a pesticide is thought to meet or exceed the criteria of risk and a "rebuttable presumption" of risk is found to exist. To rebut this presumption successfully, the applicant must prove that use of the pesticide will not result in significant acute or chronic toxic effects, or that the Agency was in error in finding that the criteria for risk were met or exceeded by the pesticide. The applicant may, however, include information on benefits resulting from use of the pesticide with the evidence that is submitted to EPA.

EPA regulations further state that, in deciding upon a course of action, "...the Administrator may, in his discretion, take into account staff recommendations resulting from preliminary analysis, if any, concerning the balancing of risks against benefits" (40 CFR 162.11 [a] [5] [iii]). The EPA staff is not specifically required by the regulations to conduct a risk/benefit analysis at this time and, if such an analysis is made, the Administrator may choose to ignore it. Even if a staff analysis is made which shows that benefits exceed risks, the regulations limit the Administrator's options on the course of action that may be taken when a decision has been made on the basis of the preliminary evaluation that the pesticide meets or exceeds EPA's criteria of risk. The Administrator may issue a notice that registration is denied or cancelled or a notice of intent to hold a hearing (40 CFR 162.11 [a] [5] [iii]), but cannot, at this stage, decide to register a pesticide product.

Thus, despite the fact that FIFRA, as amended, requires determinations about the unreasonable adverse

effects of a pesticide to take into account not only criteria of risk, but also any economic, social, and environmental costs and benefits resulting from the use of a pesticide, it is not until the last stages of EPA's decision making that Agency regulations require consideration of benefits as against risks. During a hearing before a final order of denial or cancellation of a registration, EPA regulations permit an applicant to sustain the burden of proof that the pesticide should be registered--even when it meets or exceeds the criteria of risk--by showing that the risks are outweighed by the economic, social, and environmental benefits of use (40 CFR 162.11 [b] [1] [i] [C]).

The Committee on Pesticide Decision Making believes that EPA regulations should be changed to require consideration of the relative risks and benefits of a pesticide's use at an earlier stage in the Agency's decision-making process. This would enable EPA to determine whether a particular pesticide clearly has benefits which far outweigh the risks of a proposed use without the need to hold a hearing that may be costly to the applicant and to the government and that may produce the same result as a careful risk/benefit analysis.

Recommendation

- EPA regulations (40 CFR 162.11 [a] [5] [iii]) should require, and not simply permit, the consideration of benefits in determinations of whether to issue a notice of intent to deny or to cancel a registration. This would conform with Section 2 [bb] of FIFRA, as amended.

Responsibility for Risk/Benefit Analysis in EPA

The OPP Criteria and Evaluation Division (CED) is responsible for preparing documents on the risks and benefits resulting from the use of pesticides that are being reviewed for registration or reregistration. Analysis of risks is done by the Metabolic Effects Branch and by the Ecological Effects Branch of CED, while the analysis of benefits is done by the Economic Analysis Branch.

The only guidelines for the assessment of benefits that the Agency has published are contained in its administrative procedures, "Health Risk and Economic

Impact Assessments of Suspected Carcinogens" (U.S. EPA 1976). These procedures represent an interim administrative tool for the Rebuttable Presumption Against Registration process and were not intended to serve as a complete or final method for determining the economic benefits and risks resulting from the use of a pesticide. The procedures were critized, however, by the Moss Subcommittee on Oversight and Investigations for limiting the cost factors to be considered to such immediate factors in pesticide use as costs to the user, productivity changes, and the effect on retail food prices (U.S. Congress, House 1976). The guidelines did not include such cost factors as death, suffering, or environmental degradation, which the subcommittee thought should also be assessed in risk/benefit analyses.

While the Committee on Pesticide Decision Making recognizes the purpose of EPA's interim guidelines, it believes that the Agency should develop more complete procedures for evaluating the risks and benefits of pesticide use and should then publish the proposed procedures for review and comment. Several recent reports (Kennedy et al. 1975, NRC 1975a, Edwards and Langham 1976) would be helpful to EPA in developing this document.

Cost/Benefit, Risk/Benefit, and Trade-off Analyses

Much of the controversy over the regulation of pesticides results from the difficulty of finding acceptable methods for quantifying the beneficial and adverse effects of these chemicals. If questions concerning pesticide use and regulation are to be resolved on a factual rather than an emotional basis, however, substantive factors of this kind must be carefully delineated and assessed.

Economic data are vital in any cost/benefit or risk/benefit analysis in the pesticide decision-making process. The need for such data was recognized, for example, in a report of the National Academy of Sciences which recommended that Congress give high priority to funding large-scale experiments to measure the economic consequences of alternative pest control methods, including pesticides, biological controls, cropping methods, use of pest-resistant varieties of plants, and the like (NRC 1975b).

The argument for considering the economic effects of pesticide regulation is one of relatively long standing (Headley and Lewis 1967). When pesticides effectively control pests, economic benefits may result from increased agricultural productivity, the protection of forests and building structures from the ravages of pests, and the control of disease vectors. On the other hand, society must expend finite resources when it makes use of pesticides. There also may be indirect costs in terms of deleterious effects on the environment, people, farm animals, pets, nontarget insects, wild mammals, birds, fish, and plants, including any chronic problems resulting from long-term exposures to pesticides.

It is extremely difficult to calculate all of these costs involved in the use of pesticides, particularly those that are indirect costs. For example, it is difficult to quantify the degree of risk, if any, for each species or individual in a species. It is hard to arrive at a monetary amount or even a range of figures that would be universally accepted as the cost of a possible increased incidence of cancer or of other risks to human health, because calculations of this kind involve many complex factors such as earnings lost (one way to measure the economic value of human life). A report by the National Academy of Sciences has explored in some detail the problems encountered in using a mathematical approach to decision making in the regulation of chemicals in the environment (NRC 1975a). The report noted that:

> Decisions about regulating chemicals in the environment always involve values about which the affected parties disagree; thus the values of the decision maker will play a crucial role in the outcome. There is no satisfactory way to summarize all the costs or benefits of regulatory options in dollars or other terms which can be mathematically added, subtracted, or compared. In short, there is no substitute for an experienced decision maker exercising good judgment. However, the techniques developed by decision theory and benefit-cost analysis can provide the decision maker with a useful framework and language describing and discussing trade-offs, noncommensurability, and uncertainty. They can also help to clarify the existence of alternatives, decision points, gaps in information, and value judgments concerning trade-offs.

A trade-off analysis has been suggested as the best method to evaluate the costs and benefits resulting from the use of chemicals (NRC 1975a, Abel 1976). This approach is adapted from the traditional cost/benefit analysis, which makes use of dollars or some other common unit; however, the trade-off analysis also permits the use of descriptive information for factors that are difficult to measure and, as suggested by its proponents, it "preserves more detail for the decision maker".[1] The Committee on Pesticide Decision Making believes that an explicit analysis of the benefits and risks of pesticide use should become part of EPA's decision-making procedures. As has been suggested in another National Academy of Sciences report, a "systematic and well documented analysis could substantially improve the quality of EPA decisions by providing a framework for discussion and for public understanding of the factors that enter the decision process" (NRC 1977a).

The use of a matrix is a way to summarize all the information that has been derived from such a trade-off analysis. While most of the decisions involved in such an analysis are complex and include a myriad of detail, the matrix permits the preservation only of those factors that have the highest priority in decision making. An example of a trade-off matrix for pesticides, which is adapted from one devised by Abel,[1] is shown in Figure 2.1. Before this detailed analysis is done for regulatory decision making on pesticides, it may be advantageous to do a mini-study as a screening step early in the decision-making process. A more complete analysis then might be done only when a major or complex trade-off decision is needed. The Administrator should also be aware of the fact that trade-offs for different uses of a pesticide may vary greatly, depending on the availability of alternative pest control methods, resistant varieties of a crop, and other factors.

Because the trade-off matrix for pesticides shows all the decision maker's alternatives in columns, the shift in effects among the available options and the impact of a particular decision can be readily seen for each effect that is analyzed. This facilitates the comparison of all administrative alternatives that have a common denominator and that are directly comparable. The different categories of effects, however, are likely to be expressed in terms that cannot be related to a common denominator and, therefore, the various categories cannot be objectively and quantitatively compared. One alternative that should be part of every

EFFECTS	COMMENTS (Uncertainties about quality and extent of data, other concerns)	ALTERNATIVES						
		No action taken	Ban immediately	Phase out	Restricted use[a]	Additional label restrictions[b]	Substitutes[c]	
							Pest control A	Pest control B
I. Risks								
A. Health								
1. Lost person years								
2. Lost activity days								
3. Population exposed								
B. Environment								
1. Nontarget species								
2. Vegetation damaged								
3. Animal losses								
4. Endangered species								
5. Aesthetics								
6. Recreation								
II. Economic								
A. Consumer surplus								
B. Producer surplus								
C. Costs of production								
1. Capital								
2. Operating								
D. Other costs								
1. Training applicators								
2. Enforcement expense								
3. Government administrative expense								
E. Plants closed								
F. Jobs lost								
III. Distribution								
A. Population group benefited								
B. Population group adversely affected								
C. National								
IV. International								
V. Agricultural								
A. Production								
B. Commodity prices								
C. Retail food prices								
D. Agricultural economy								
VI. Pesticides Used								
A. Amount of pesticide								
B. Amount of substitute A								
C. Amount of substitute B								

a. Reclassify the pesticide from general use to the restricted-use category, which requires that it be used only by certified applicators.
b. Place conditions on the use of the pesticide by changing or adding to the restrictions on the label.
c. Substitutes can be another pesticide or other pest control methods.

SOURCE: Adapted from Abel, F. H. (1976) The Use of Economic Information in Registering Pesticides, an unpublished paper prepared for the Committee on Pesticide Decision Making.

FIGURE 2.1 Trade-off matrix for pesticide decision making.

analysis is a case in which no action is taken and the pesticide is not subjected to any regulatory constraints. When applicable, another component, shown in the last column of Figure 2.1, should be an analysis of trade-offs under alternative pest control methods, which may or may not involve the use of a pesticide. A comparison of the columns in Figure 2.1 will show the net change in effects, whether adverse or beneficial, between the case of no regulation and the use of a selected option or options. A special column in the trade-off matrix is provided for comments, so that major items or issues that cannot be captured by other components of the matrix can be displayed.

Health effects, the first category on the suggested trade-off matrix, are calculated in terms of years of life that may be lost as a result of premature death, days of activity that may be lost as a result of ill health (this could be subdivided into days lost to mild and to serious illness), and the size of the population that will probably be exposed to the pesticide. All health effects would not necessarily be negative; for example, a pesticide might prevent death or illness by control of mosquitoes that transmit malaria.

Currently, EPA limits its consideration of health hazards in pesticide use to a determination of whether the toxicity of a pesticide meets or exceeds the Agency's criteria for unreasonable adverse effects to humans or to the environment. This is an acceptable first step in the decision process, and the fact that a pesticide does or does not trigger one or more of these criteria should be reported in the column for comments. There is still not adequate information, however, for a risk/benefit trade-off decision on health effects. Information on the manner and extent of the pesticide's use and the cumulative exposures likely to occur are also needed by the decision maker to determine the number of adverse health effects (i.e., illnesses and deaths) that can be expected to become "costs" or "risks" to society. While a determination of the effects that a pesticide may have on health is a scientific judgment, the question of whether these effects are acceptable, as compared to the benefits resulting from a pesticide's use, is a subjective value judgment to be made by the decision maker. The distinction between the scientific basis for determining the level of risk and the judgmental basis for determining the acceptable level of risk is discussed in greater detail in Lowrance (1976).

The health category on the matrix also includes the effects of a pesticide on the environment. Environmental effects include the effects on nontarget vegetation and animals, on endangered species, and on the aesthetic and recreational environment of humans. Of the many different kinds of possible environmental effects resulting from the use of a pesticide, only a few are likely to be important in any one decision.

Economic effects, the next category on the matrix, are important in the risk/benefit analysis only if conversion of the number of effects into dollar values is useful to the decision maker. Edwards and Langham (1976) present a theoretical discussion and a case study of quantifying effects in economic terms and conducting a cost/benefit analysis, and the limits and possible problems resulting from such an approach are discussed in a National Academy of Sciences report (NRC 1975a). Direct economic effects on the trade-off matrix might include a lower cost to consumers for food produced with the aid of pesticides and any increased cost to farmers in producing the food. The measurement of direct economic effects is discussed in detail in Kennedy et al. (1975), Edwards and Langham (1976), and Headley and Lewis (1967). The indirect economic effects of a pesticide's use may include changes in employment, training programs, equipment purchases, and capital costs.

The next matrix category is distribution effects, which are shown in terms of the groups of people--age groups, worker groups, etc.--and the total number of people who are expected to benefit or to be adversely affected by a decision on a pesticide.

The use of a category on international effects in this matrix is in recognition of the fact that pesticides are a component of international trade. While EPA cannot, of course, make decisions about what other countries should do in relation to their pest control needs, the Agency does have a responsibility to consider the effect of its decisions on other peoples in the world. The Committee on Pesticide Decision Making has no specific suggestions for the kinds of data that should be considered in this category and suggests that the Agency seek comments from the U.S. Agency for International Development (AID) and appropriate international organizations, such as the Food and Agriculture Organization and the World Health Organization. (See Chapter 5 for a discussion of the international impacts of EPA pesticide regulations.)

The agricultural portion of the matrix calls for gross measures of the economic effects on agriculture of a decision that is made on a pesticide. The four measures used in this category meet the requirement of the 1975 amendments to FIFRA that, in proposing action on a pesticide, EPA must take into account the impact of that action "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy" (Sec. 6 [b] [2]). The legislation does not specify how the impacts on agriculture are to be measured or traded off. Among the issues involved are a decrease in agricultural production that may occur when pesticides are not used, and the increase likely to occur in consumer costs if production falls.

The final section of the trade-off matrix calls for an accounting of the quantities of pesticides that will be used under alternative options for action.

The detailed procedures that EPA uses to gather and evaluate data for the trade-off analysis of risks and other costs compared to the benefits resulting from pesticide use should be developed after consultation with scientists in other government agencies at both state and federal levels, scientists in universities and colleges, and other people who are knowledgeable about the risks and benefits that may occur when specific chemicals are employed by agriculture, industry, or in home uses. Consultation and review outside the Agency will help to gain public understanding and acceptance of the complex trade-off process.

Recommendation

- EPA should develop detailed procedures for assessing the risks and benefits resulting from the use of a pesticide and for analyzing trade-offs between the risks and benefits. In doing so, EPA should seek outside review and comment from the scientific community.

Adequacy of Data on Economic Losses

Unfortunately, adequate economic data usually do not exist to make accurate estimates for a trade-off matrix of the savings that can be realized through the use of pesticides on crops, forests, or structures or to estimate losses that would be sustained if a

pesticide were not available. While this shortcoming does not destroy the usefulness of a trade-off matrix as a decision-making tool, it must be taken into account when the matrix is used. In order to determine the effects of using a pesticide for cutworm in corn, for example, it is important to know how likely it is that a cutworm infestation will occur, how many acres might be infested, and the potential extent of crop losses.

There are a number of reasons why adequate economic data for risk/benefit analyses are not available. First, there is the fact that registrants of pesticides are required to submit data relative to the risk categories established by EPA and on the efficacy of a candidate compound against target pests, but they are not required to provide data showing the impact of a pesticide compound on agricultural productivity. Consequently, high quality data on the historical or potential ability of a pesticide to prevent losses, gauged in terms of monetary value, are not available for use in EPA's cancellation or suspension hearings. Moreover, data showing the impact on productivity are difficult to obtain. The development of such data requires estimating the acreages that have been treated or that will be treated, the crop yields and, perhaps, the prices of agricultural commodities if a pest is not controlled. Estimates that are based on the use of a pesticide in test plots may not be adequate to meet these data requirements because the plots may not provide the same results as would be obtained under field conditions. When a pesticide has more than one use, it may be particularly difficult to analyze its potential economic benefits because it will be necessary to determine how much money should be assigned to the prevention of losses in each use of the pesticide.

Benefit determinations are also complicated by the economics of pesticide use. A determination of economic benefits resulting from the use of a pesticide cannot always be made simply by comparing data on crop yields with and without the pesticide. There is a difference between striving for the maximum biological yield obtainable and the most favorable economic return possible. It might not be economically desirable to strive for the highest biological yield.

In making risk/benefit determinations, EPA needs full access to all available information on pesticide use. In the past, there has not been a full exchange of information between EPA and USDA for this purpose,

in part because of the adversary nature of the EPA cancellation and suspension proceedings, in which the USDA role tended to be one of opposition to the cancellation of pesticide compounds. A memorandum of understanding between EPA and USDA, which was signed in December 1976, should bring about greater cooperation between the two agencies in developing the objective and accurate data that EPA requires for the regulation of pesticides. The memorandum establishes the principles and mechanisms whereby the two agencies will gather the information for risk/benefit assessments when a pesticide enters the RPAR process because it is presumed to create an unreasonable adverse effect on humans or the environment. The EPA/USDA memorandum states:

> It is agreed that this [cooperative effort] will be done in a manner which recognizes and utilizes the capabilities of each agency to the greatest feasible extent in either making resources available to the other agency or for the joint planning and execution of activities. Consistent with its broad agricultural responsibilities, USDA and State/universities are recognized as major sources of information on pesticide uses, relative effectiveness of pesticides and the importance of specific pesticide uses for agricultural and forestry purposes...EPA is recognized as a basic source of information on pesticide registration and environmental and health hazards associated with pesticide use. Both agencies have important contributions to provide on environmental aspects of pesticide use.

As long as little or no regulatory pressure was exerted on the use of pesticides and as long as pesticides were cheap, the profitability of using pesticides seemed self-evident. Their effectiveness was well-known or accepted in terms of the costs of pest control for such important crops as cotton, tobacco, apples, vegetables, and certain cereals. As a result, there was not a compelling need for farmers and agricultural researchers to give a high priority to studies of the monetary effects of pesticide use. The U.S. Department of Agriculture has not had an ongoing program to evaluate the economic feasibility of pest control, for example, primarily because other matters were more urgent in the period before the public became aware of the hazards resulting from pesticide use and before more stringent regulatory provisions were

enacted in FIFRA, as amended. In 1976, in accordance with the memorandum of understanding between USDA and EPA, USDA organized a pesticide impact assessment program that draws on information and expertise from State Agricultural Experiment Stations (SAES). This program has two weaknesses: it is concerned principally with pesticide compounds that are being challenged by the RPAR process of EPA and it is, therefore, a reactive program; and the SAES data on pest damage are derived in many instances from efficacy tests in small plots rather than from field situations. However, the impact assessment program does have a research component, which indicates that the USDA recognizes a need for additional data.

TOLERANCES

Pesticides that are used to control pests during the production and storage of agricultural commodities may result in residues of chemicals on or in agricultural food or feed. To protect the safety of our food supply, Congress has provided for the regulation of such residues in the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. Section 408 of the Act (21 USC 346a) pertains to the establishment of tolerances (the allowable residue level) for pesticide chemicals in or on raw agricultural commodities; Section 409 of the Act (21 USC 348) deals with food additives, which include pesticides.

A pesticide that is to be used on a human food or animal feed crop cannot be registered until EPA establishes a tolerance or an exemption from the requirement for a tolerance (see the section on Exemptions in this chapter) for that pesticide use. Because it would be impractical for FDA to enforce tolerance levels on foods at the point of consumption, the tolerances are established by EPA on raw agricultural commodities.

Under EPA regulations governing the establishment of tolerances (40 CFR 180.7), it is the responsibility of the registrant of a pesticide to petition the Agency for a proposed tolerance level or an exemption from a tolerance. The petitioner must include these data on the pesticide's toxicology, residues, and analysis, as specified in Section 408 of FFDCA:

- the name, chemical identity, and composition of the pesticide;

- the amount, frequency, and time of application of the pesticide;

- full reports of investigations made with respect to the safety of the pesticide;

- the results of tests on the amount of residues, including a description of the analytical methods used;

- practical methods for removing residues that exceed a proposed tolerance;

- proposed tolerances for the pesticide; and

- reasonable grounds in support of the petition.

Establishing "Safe" Residue Levels

The evaluation of pesticide residues in food in order to establish tolerance levels for these residues is a complex undertaking from a regulatory standpoint. There are some inherent difficulties in the use of laboratory procedures, such as tests on experimental animals, to determine with mathematical precision the hazards that a pesticide may present to human beings. There are also limitations in the ability of assay methods to measure residues of pesticides or other additives in foods when they are present at low levels. The Food and Drug Administration, which has the regulatory responsibility under Section 409 for nonpesticide additives in food, has commented on these limitations in its Criteria and Procedures for Evaluating Assays for Carcinogenic Residues (U.S. DHEW 1977):

> ...any introduction of a compound (whether or not carcinogenic) is likely to leave minute residues in edible tissues that are below the level of detection of any known or likely to be developed method of analysis...Thus, when a tissue is examined with an assay having a lowest limit of measurement of 1 ppb [part per billion] and no interpretable response is observed, the analyst can only conclude that the compound under analysis is not present at levels of 1 ppb and above. It can never be concluded that the compound is "not present" in the absolute sense.

Faced with such complications, a government agency that regulates the use of chemicals is forced to seek an administratively tenable position between the unknowns of science and the mandates of regulatory legislation. For example, although Section 409 of FFDCA specifies that the government shall establish regulations "prescribing the conditions under which such additive may be safely used," the government agencies that carry out this mandate must make the determination of safety on the basis of the best knowledge that is available; of necessity, the agencies must perceive the levels that they permit for the use of chemicals as "acceptable," or toxicologically insignificant, rather than as demonstrably "safe." The language of Section 408 of FFDCA, which is somewhat broader than Section 409 in its safety requirements, calls for "experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health." This section also says that appropriate consideration should be given to other relevant factors, such as the need for an adequate, wholesome, and economical food supply.

In its evaluation of proposed tolerances or exemptions from tolerances, EPA requires petitioners to provide a minimum amount of data on toxicological studies, which can be summarized as follows:

- studies of acute toxic effects to establish the lethal dose for various kinds of exposure to a pesticide, such as oral and dermal;

- 90-day animal feeding studies to determine the subacute toxic effects of a pesticide;

- lifetime feeding studies in animals to determine the chronic effects of a pesticide (primarily the oncogenic effects);

- metabolism studies to determine the metabolic fate of the pesticide chemical and its possible concentration in tissues;

- reproduction studies in animals to determine whether the pesticide causes any physical, physiological, or behavioral abnormalities;

- studies of teratogenic effects of a pesticide; and

- studies of the mutagenic effects of a pesticide.

Other factors that enter into EPA decisions on establishing tolerance levels for the residues of a pesticide in various foods, or in permitting an exemption, are scientific judgment of the data that have been submitted to the Agency; the chemical properties of the pesticide, including the potentiating effect that the chemical may have through interaction with other substances; the pattern of use for the pesticide; the probable exposure of humans to similar chemicals; and the cumulative contribution to the human diet by commodities that bear similar residues.

EPA regulations for the establishment of tolerances contain a definition of "negligible residue" which appears to permit a less rigorous procedure in some instances (40 CFR 180.1 [l]). This definition is:

> The term "negligible residue" means any amount of a pesticide chemical remaining in or on a raw agricultural commodity or group of raw agricultural commodities that would result in a daily intake regarded as toxicologically insignificant on the basis of scientific judgment of adequate safety data. Ordinarily this will add to the diet an amount which will be less than 1/2,000th of the amount that has been demonstrated to have no effect from feeding studies on the most sensitive animal species tested. Such toxicity studies shall usually include at least 90-day feeding studies in two species of mammals.

This definition in EPA regulations does not agree with the present data requirements of EPA, which include data based on investigations of the chronic toxicity of a pesticide in lifetime feeding studies on animals.

While chronic toxicity is a major concern in the use of pesticide chemicals, this Committee questions whether such studies should be required in all instances. In some cases, scientific review by the Agency of the level of risk posed by a chemical may permit the determination of a tolerance level without requiring 2- to 3-year studies, depending on such factors as the limited proposed use of the pesticide, the family of compounds to which it is related, and test data showing that few or no residues of the chemical are likely to be present in food.

The Committee does not imply that the Agency should discontinue its vigilance in the regulation of pesticides or its concern for the oncogenic effects of certain pesticides, but only that expensive and extensive chronic feeding studies should not be required where there is clear scientific evidence that they are not necessary.

Recommendation

- By emphasizing scientific data and judgment, EPA should in some instances permit use of a concept similar to that of negligible residues, as defined in 40 CFR 180.1 (l).

EXEMPTIONS FOR FEDERAL AND STATE AGENCIES

Congress recognized that the inherent constraints in the pesticide registration process might impede the timely response by EPA to critical situations of pest infestation and damage. Section 18 of FIFRA, as amended, provides a mechanism to make it possible for federal and state agencies to react expeditiously to emergency conditions of this kind. Section 18 says:

> The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption.
>
> The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

EPA regulations for exemptions under Section 18 (40 CFR 166) state that consideration will be given to three types of exemptions: specific (for pest outbreaks of an emergency nature); quarantine-public health (to prevent the introduction or spread of a foreign pest); and crisis (for critical situations in which there is not enough time to get a specific exemption).

The legislative provision for exemptions offers egulatory flexibility when there are critical outbreaks of pests and no pesticides have been registered for the uses that are needed to control or

eradicate them. The successful use of this provision, however, depends upon the attitudes, intentions, and prudent judgment of the parties involved; an unsupported proclamation of an emergency should not be enough to set this provision in motion. On the other hand, EPA must be flexible and reasonable in its evaluation of a request for an exemption. If the Agency is overly restrictive, the intent of Congress to provide measures for meeting emergency pest control situations will not be carried out.

Timeliness is important in processing requests for exemptions because of the emergency nature of these actions. Apparently, there have been occasions when EPA failed to respond promptly to requests for an exemption. In 1976, the Florida Department of Agriculture and Consumer Services applied to EPA for a specific exemption to use Vydate L on tomatoes to control leaf miners. Vydate L is a registered pesticide, but this compound is not registered for use on tomatoes. After 10 weeks, EPA denied the request and asked for more information (personal communication from Vincent Giglio, Director, Inspection Division, Florida Department of Agriculture and Consumer Services). Currently, the EPA handling of exemptions is being reviewed by the U.S. General Accounting Office (GAO) as part of a review of EPA's special registration programs (the other programs under review are experimental use permits, Section 5 of FIFRA, as amended; and state registration of pesticides to meet special local needs, Section 24 [c]). GAO has uncovered some problems with respect to the time it has taken EPA to approve or deny requests for exemptions, although there has been some recent improvement in this area.

Recommendation

- EPA should respond expeditiously to requests for exemptions under Section 18 of FIFRA, as amended, for the emergency control of pests.

PERMITS FOR EXPERIMENTAL USES

Before a chemical is registered as a pesticide, it is subjected to a multistage testing process. The substance is first screened in the laboratory for its efficacy against a pest species and its effect on other species. If this efficacy is exhibited, the substance

is put through laboratory or greenhouse tests. If the researcher decides that the substance appears to have value as a pesticide and should be tested in field plots in order to collect the information needed for registration with EPA, an EPA experimental use permit is required.

EPA supervises the use of pesticides under these experimental permits. If the Agency determines that an experimental use may result in any residue on or in food or feed, it may establish a temporary tolerance level for the residues before issuing a permit or require that the food or feed be disposed of in a manner which will not endanger humans or the environment. In general, EPA regulations for experimental use permits provide reasonable protection against hazards that might result from the testing of new pesticides or the testing of registered pesticides for new uses.

EPA regulations for experimental use permits do not, however, specify a period of time within which the Administrator must rule on a request for these permits. It is important that the Agency act expeditiously on the requests so that researchers can plan a field program and commit research facilities well in advance of a growing season.

Recommendation

- EPA should rule on applications for experimental use permits within 90 days after an application is received.

MINOR USES OF PESTICIDES

A special problem exists in the registration of pesticides for minor uses. These uses for pesticides may involve major pests on minor crops or minor pests on major crops, but in either case the total volume of the pesticide that is used is small compared to the amount used for the control of major pests on livestock and on such crops as cotton, grains, and soybeans.

Manufacturers of pesticides are reluctant to seek registration of their products for minor uses because the market potential for these uses is not great enough to justify the costs of developing data required for registration. Manufacturers are also concerned with their potential liability for crop damage because their

costs for legal defense might be large in relation to the revenues that are obtained from a pesticide that is sold for minor uses.

A number of pesticide uses of a minor nature occur in agriculture. Many fruit and vegetable crops that are grown in relatively small quantities, but that make up a significant part of our diet, are an example of the kinds of crops on which pesticides find an essential or important, but minor, use. Pesticides also have minor uses in public health, structural, institutional, vertebrate, aquatic, ornamental, and veterinary pest control programs. As an example of the magnitude of the problem that exists when pesticides for minor uses are not available, Cornell University has compiled a list of more than 2000 minor uses for which there are no federally-registered pesticides. Interim registrations were obtained for approximately 30 food and 870 nonfood uses in October, 1975. About 200 of these uses are to control pests on food, feed, forage, and livestock and about 1800 of the uses are for trees, shrubs, and ornamental plants (personal communication from James E. Dewey, entomologist, Cornell University).

Before FIFRA was amended in 1972, the federal government did not explicitly prohibit uses of pesticides that were not included on a pesticide label as long as these uses did not result in residues exceeding tolerances established under the Federal Food, Drug, and Cosmetic Act. Even this requirement did not have to be met if pesticides were not distributed and sold in interstate commerce, except for those cases where state registration may have imposed limitations. Pesticides in intrastate commerce were not affected because they were not subject to federal regulation.

Although the amendments to FIFRA do not mention minor uses of pesticides, these uses are affected by the more stringent requirements of this legislation; by EPA's strict interpretation of Section 12(a)(2)(G), which deals with labeling; and by the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, for the establishment of tolerances for pesticide residues in food and feed. The pertinent provisions of FIFRA, as amended, are:

Sec. 3(a) requires federal registration of all pesticides sold in intrastate and interstate commerce. State registrations are preempted.

Sec. 3(c)(2) gives EPA authority to specify the kinds of data which are required to support applications for the registration of pesticides. EPA has determined that any application for registration or reregistration, or for the amendment of an existing registration, must be accompanied by supporting data for each specific use that is sought for the pesticide. The Agency does not, for example, permit extrapolation of data from tests that have been made to support the registration of a pesticide for a particular target pest to the use of the same pesticide on another pest, even when these pests are closely related and the rates of application and other conditions of use are the same.

Sec. 12(a)(2)(G) makes it unlawful to use any registered pesticide in a manner inconsistent with its labeling. As noted above, EPA has interpreted this section to mean that each specific use of a pesticide must be registered. This use then appears on the product's label, and in most cases other uses are unlawful. (Exceptions have been made by EPA for a few pesticides; see the discussion below of Pesticide Enforcement Policy Statements.)

Sec. 24(c) permits states to register pesticides for special local needs, which include many minor uses. State registrations are subject to cancellation by EPA within 90 days if disapproved by the Administrator within that period.

The report of the Senate Committee on Agriculture and Forestry (U.S. Congress, Senate 1972) indicates the intent of Congress in Section 24(c) to permit flexibility in the registration of pesticides by states to enable them to deal with local problems:

> The purpose of this subsection is to give a State the opportunity to meet expeditiously and with less cost and administrative burden on the registrant the problem of registering for local use a pesticide needed to treat a pest infestation which is a problem in such State but is not sufficiently widespread to warrant the expense and difficulties of Federal registration.

It has been difficult for states to make use of Section 24(c), however, because EPA cannot permit a state to register pesticides under this Section unless a tolerance has been established for residues of the pesticide in or on the particular food or feeds for

which the Section 24(c) registration is being sought (U.S. EPA 1977b).

Most pests on minor crops, and minor pests on major crops, can be adequately controlled with registered pesticides that are already on the market. In such cases, data on the hazards that a pesticide may present to humans or to the environment have already been developed. The principal obstacle to registration of these pesticides for minor uses is the fact that data on the efficacy and residues of each pesticide must be developed for every use. The data on efficacy must demonstrate that a pesticide will effectively control a target pest without harm to the host plant under agricultural and environmental conditions that are representative of areas where the pesticide will be used. The data on residues, which are required to set residue tolerances, must also be representative of geographic areas where the pesticide will be used (U.S. EPA 1977b).

EPA has tried to remove some of the barriers to the registration of pesticides for minor uses by encouraging applicants for registration to broaden label directions, e.g., by using such phrases as "and similar corn root pests" and "similar broadleaf weeds in the home lawn." As a result of this policy, EPA has permitted the broadening of label directions for a few pesticides when there were no indications that problems would occur if these pesticides are used on related pests. To assuage the fears of manufacturers and users that EPA enforcement actions might be taken on the grounds of "use inconsistent with the label" for these pesticides, the EPA Pesticides and Toxic Substances Enforcement Division has issued Pesticide Enforcement Policy Statements (PEPS), each defining the kinds of label deviations that are permitted for a particular pesticide and against which enforcement action will not be taken.

It is the opinion of the Committee on Pesticide Decision Making that a reliance upon prosecutorial discretion, which in effect is what the PEPS do, is a poor way to regulate the use of pesticides. The PEPS concept of conditionally grouping similar target species on a label, however, might be useful if it were to be applied across the board to pesticides that have minor uses and that do not present a hazard to humans or to the environment. On this basis, the thrust would be positive rather than negative; furthermore, the grouping would represent basic EPA policy rather than a

prosecutorial arrangement in which exceptions are made to Agency policy.

EPA might also consider grouping similar crops for the purpose of estimating pesticide residues on the crops and to establish tolerances. The crop groupings might be made in accordance with proposals that various researchers have made for grouping foods to estimate residue levels.[2] It will be necessary, however, for EPA to determine whether the provisions on pesticide residues in the Federal Food, Drug, and Cosmetic Act will permit this use of the grouping concept.

Recommendation

- EPA should investigate the scientific and regulatory feasibility of adopting the concept of grouping similar pests and similar crops when the data on these pests and crops are related and demonstrate the safety and efficacy of pesticides.

Another approach to the problems of pesticides that are used for minor purposes is to provide federal support for the development of data in cases where industry is unable to justify the costs of research in terms of the economic return from sales. The Interregional Research Project Number 4 (IR-4), which is located at the New Jersey State Agricultural Experiment Station, was begun in 1964 to obtain the data required for establishing residue tolerances in food crops as part of the registration of pesticide products. IR-4 has been expanded to include the gathering of data on residues for the registration of pesticides for minor uses and also has begun to move into the area of nonfood crops (U.S. EPA 1977b). The program is federally funded through the Cooperative State Research Service of the U.S. Department of Agriculture.

Although some relief from the problems involving the minor uses of pesticides may be obtained through measures of this kind, this Committee believes that these problems also require changes in FIFRA, as amended, so that there is an improved statutory basis for dealing with the question of pesticides that have minor uses. The changes that this Committee proposes would be to specify the interpretation of the present statutory expression, "it shall be unlawful...to use any registered pesticide in a manner inconsistent with

its labeling." The legal interpretation of this phrase should be clearly defined to allow the application of a pesticide in a concentration less than that specified on the label, and to allow for the use of the pesticide against a pest that is not specified on the label, as long as the application is made to a crop or site that the label does specify. These changes are incorporated in Senate proposals for the further amendment of FIFRA. This Committee endorses the changes contemplated by the recent Senate Bill, S1678, which agree in principle with the following Committee recommendation:

Recommendation

- EPA should define the phrase "it shall be unlawful...to use any registered pesticide in a manner inconsistent with its labeling" as follows:

  -- application to a crop, animal, or site not included in the labeling claims, or

  -- application of an amount of active ingredient, product per unit area, or space exceeding those on the labeling, or

  -- failure to follow restrictions or limitations on the labeling.

RESEARCH

The legal authority for EPA's research on pesticides is stated in Section 20 of FIFRA, as amended:

> The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall give priority to research to develop biologically integrated alternatives for pest control. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

Current Status

Research on pesticides conducted by EPA scientists is strongly oriented toward the Agency's regulatory and decision-making functions. OPP investigations of pesticide products, for example, have a practical and specific orientation and primarily consist of checking the test results, efficacy claims, labels, and other information that have been submitted to OPP for the registration, reregistration, or setting of tolerance levels for pesticides (personal communication from Jean Pulliam, Chief Research Coordinator, OPP). Because OPP considers its laboratory investigations to be informational in character rather than as research in an academic sense, the functions of these laboratories are described in Chapter 3 of this report, which describes the scientific and technical information used by EPA in its regulation of pesticide chemicals. In addition, OPP has also conducted and supported special studies in a number of broad categories: effects of pesticides, alternative pest control methods, laboratory methods and quality control, recovery and conversion of pesticide wastes, cost/benefit assessment methods, and assessments of unreasonable adverse effects resulting from the use of pesticides (Grosse 1976).

The pesticides research program of the EPA Office of Research and Development (ORD) is also directed toward support of the Agency's regulatory responsibilities, but the program has a somewhat wider focus than the information and research related activities of OPP. The ORD operating plan for the 1978 fiscal year in the area of research on pesticides includes these activities (U.S. EPA 1977c):

> Health effects research--evaluation of _in vivo_ and _in vitro_ testing for potential carcinogenicity of pesticides; research on the health implications of "new generation" pest control agents such as insect viruses, pathogenic bacteria, hormones, attractants, etc.; the development of analytical analyses and measurement methodologies to meet requirements for detecting small quantities of pesticide residues in environmental samples and in human tissue; evaluations of human exposures to pesticides in various living and working situations; and the development of predictive models for assaying human dose/response relationships to pesticides.

Ecological effects research--studies of the effects of pesticides on sensitive organisms; effects of pesticides on ecosystems; routes and rates of pesticide movement through ecosystems; fate of pesticides in the ecosystem; and the frequency and significance of carcinogens and viruses in the environment.

The budget submission for pesticides research in the ORD Operating Plan for the 1978 fiscal year was $8.3 million, of which $1.1 million was to fund contracts, $1.1 million was for grants, and $75,000 was for interagency agreements, with the balance to be used by the Agency for its own research and administrative expenses (U.S. EPA 1977c). This budget submission was somewhat smaller than the $10.8 million for ORD research on pesticides for the 1977 fiscal year and was about the same as the $8.8 million that was spent for this purpose in the 1976 fiscal year (U.S. EPA 1977a).

Coordination of Research

Research relating to pesticide chemicals done by EPA, other federal agencies, State Agricultural Experiment Stations, universities, and other groups is not coordinated in any formal or effective way, although attempts to coordinate some of the information produced in this research have been made (see Chapter 3 of this report for a discussion of this problem). A recent study by the National Research Council emphasized the importance of coordinating the many research programs relating to environmental protection (NRC 1977c):

> It is not likely that EPA will ever have the financial resources to perform or sponsor all the research needed to support its responsibilities, in which hundreds of billions of dollars are at stake. Indeed, we doubt that it would be wise public policy to spend the enormous sums required through a single agency, however central its role. Our doubts arise from a recognition of the legitimate substantive interests of other agencies, of the great range of scientific disciplines involved in this research, and of the difficulties a regulatory agency inevitably faces in maintaining capabilities in basic scientific research...it appears to us necessary to marshal for environmental

protection more of the national research and development effort than can or should be handled by EPA alone.

The need to coordinate environmental research to prevent duplication and to enable EPA to get maximum benefits from the limited funding available for this purpose is one of the major problems facing the Agency. It is difficult to accomplish this goal, however, for a subject area as large and as complex as environmental protection. In this field, research is scattered among many agencies and other institutions, each with its own compelling needs or mandates and with its own budgetary constraints and requirements for the timeliness of research information. Among the mechanisms that are available to coordinate the planning and conduct of research under such diverse conditions are interagency groups and coordinating committees, formal interagency agreements, and memoranda of understanding between agencies or between agencies and the private sector (U.S. Congress, Senate 1962).

To obtain coordination of research on pesticides within EPA, and to facilitate coordination with pertinent research elsewhere, the Committee on Pesticide Decision Making believes that all EPA research contracts and grants relating to pesticides should be cleared through ORD. Although this might present some problems for administrative and technical personnel in the Office of Pesticide Programs, these problems are likely to be outweighed by the benefits to be gained in time, cost, and the coordination of information.

Recommendation

- EPA should clear all contracts and grants for research on pesticides through its Office of Research and Development (ORD) to gain better coordination and centralized technical review of the research.

Quality Control

Proposals that originate inside the Agency or in other federal agencies for research funded by EPA are not usually subjected to external technical review (NRC 1977c). Review of proposals originating both inside and outside the Agency for research on pesticides by

scientists and other people knowledgeable about the proposed areas of investigation might ensure better project design. Such review would also help prevent duplication of effort by various federal agencies and institutions. The review process might be carried out in a manner similar to the peer review methods used by the National Science Foundation or the National Institutes of Health.

Publication of Research

Prepublication review of final reports of EPA research on pesticides is also largely done within the Agency. The project officer in the division that issued the research contract is responsible for reviewing the reports for quality control and final acceptance. When the subject matter relates to the development of patent rights for a new chemical product, the research results are sent to the appropriate company or industrial representative before they are released for publication; the results are not published if publication would involve disclosure of trade secrets or infringement of patent rights.

Publication of the results of EPA research on pesticides is an important part of the research process. It opens up access to the research findings to policymakers and to regulatory personnel in federal, regional, and state agencies, to other research scientists, and to users of pesticides, chemical companies, trade associations, State Cooperative Extension Services, and the general public. Nevertheless, EPA largely disseminates the results of its research in internal reports and usually does not publish the results or subject them to external peer review. ORD issues a quarterly bibliographic summary of all its published reports, however, which is widely distributed (NRC 1977c).

Research sponsored by ORD that is conducted by private contractors may be published by the Agency in the form of reports on completed contracts. Presumably, scientists working under contract for EPA at universities and at other research sites also seek publication in scientific journals, for the usual academic reasons, of the results of their research.

The publication in scientific and technical journals of research on pesticides usually involves some type of peer review by scientists on the journal's staff or its advisory board or by specialists to whom

articles are sent for comment before publication. Although it may take more than a year for publication in these journals, whereas the publication of reports by EPA only takes about three months, publication in scientific journals has the advantages of peer review and distribution within the scientific and technical community. Unfortunately, it may not be possible to publish the results of research both in EPA reports and in scientific and technical journals because journal editors often take the position that Agency reports constitute prior publication and they may not be willing to publish the results again. In the opinion of this Committee, the advantages of publication in scientific and technical journals outweigh the disadvantage that this form of publication is likely to take longer than does the publication of reports by EPA.

Recommendation

- EPA should seek publication of the results of its research contracts and grants in scientific and technical journals rather than in Agency reports.

Use of Research Results in Decision Making

Information on the results of EPA research is channeled through a formal decision-making sequence. Key components of this sequence include a working group that has been appointed to examine a regulatory action or standard under consideration, the EPA Steering Committee, and, finally, the EPA Administrator. (For a description of the use of scientific and technical information in the EPA decision-making process, see the report to EPA by the Environmental Research Assessment Committee of the National Academy of Sciences [NRC 1977c].)

The use that the Office of Pesticide Programs makes of research reports and other scientific and technical information is described in Chapter 3 of the present report. This Committee believes that the OPP staff should become more involved in the transfer of relevant information to administrative decision makers who are charged with interpreting and implementing the Agency's programs. As has been pointed out by the Environmental Research Assessment Committee (NRC 1977c):

> Even if the decision makers involved were all trained scientists--which they neither are nor are likely to be--they would almost certainly lack the breadth of technical experience needed to judge the validity and applicability of such diverse scientific and technical information. We therefore conclude that scientists, informed and up-to-date in their respective fields, should be responsible for gathering, analyzing, transforming, and transferring the [scientific and technical] information in a form that can be used by nonexperts.

Much of the advice that the Office of Pesticide Programs receives from advisory committees is oriented toward policy needs rather than toward the technical aspects of decision making on pesticides. The OPP should make more extensive use of multidisciplinary groups, both outside and inside the Agency, to provide better channels of communication with the scientific community on the technical aspects of its pending decisions on pesticides. This would also give the interested public a better insight into the EPA decision-making processes as they relate to pesticides.

MONITORING

The National Pesticide Monitoring Program

The importance of adequate environmental monitoring programs has been constantly reiterated by various studies, beginning with one in the early sixties by a Presidential science advisory committee (President's Science Advisory Committee 1963). This Presidential committee recommended that the federal government should develop a continuing network to monitor the levels of chemical residues in the environment. The result was the establishment of the National Pesticide Monitoring Program (NPMP) as a cooperative effort by several federal agencies. With the enactment of FIFRA, as amended, the NPMP achieved statutory status. Sections 20(b) and (c) of the law, which delegate the authority to EPA to develop and carry out a plan for monitoring pesticides in all components of the environment, state:

> Sec. 20(b) NATIONAL MONITORING PLAN.--The Administrator shall formulate and periodically revise, in cooperation with other Federal,

State, or local agencies, a national plan for monitoring pesticides.

Sec. 20(c) MONITORING.--The Administrator shall undertake such monitoring activities, including but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this Act and of the national pesticide monitoring plan. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

Historically, the NPMP monitoring of pesticide residues has been scattered among federal agencies. This situation still exists and, according to an evaluation by the Battelle Columbus Laboratories (Carroll et al. 1975), the dispersion of responsibility for monitoring residues has limited the program's effectiveness.

The NPMP is made up of these subprograms:

- Food and feed monitoring. This effort has three components--a "market basket" study which is made by the Food and Drug Administration (FDA) to determine the amount of pesticide residues in a well-balanced diet; an FDA nationwide surveillance of domestic and imported raw agricultural commodities, processed foods, and animal feeds; and surveillance by the USDA Animal Plant Health Inspection Service of residues in meats and poultry.

- Human monitoring. This program is operated by EPA in cooperation with the National Center for Health Statistics of the U.S. Department of Health, Education, and Welfare. Its purpose is to determine, on the basis of tissue samples, the incidence and level of exposure to pesticides in the general population.

- Soils monitoring. EPA monitors the presence of pesticides in cropland, noncropland, and urban soils in this program.

- Water monitoring. EPA and the Geological Survey of the U.S. Department of the Interior jointly operate this program to estimate ambient levels of pesticide residues in water and in the sediments of major drainage basins of the continental United States.

- Estuarine monitoring. EPA monitors residues in estuarine fish and fauna in this program.

- Ocean monitoring. EPA and the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration in the U.S. Department of Commerce monitor pesticide residues in ocean fish.

- Bird monitoring. The U.S. Fish and Wildlife Service in the U.S. Department of the Interior monitors residues in ducks and starlings in this program.

- Freshwater fish monitoring. Pesticide residues in lake and river fish are monitored by the U.S. Fish and Wildlife Service.

- Air monitoring. Two pilot studies were conducted by EPA in this area, but there is no regular NPMP program now in operation to monitor pesticides in air.

The Battelle study of the NPMP concluded that the program organization is essentially that of an association of subprogram directors and that overall NPMP management does not exist:

> Key project findings...indicate lack of management accountability and lack of operational continuity in the current NPMP. At present, each subprogram manager is responsible for...structuring monitoring designs, maintaining analytical quality, and reporting the collected data for his portion of the program. Since each subprogram manager is responsible to the particular agency by which he is employed, and since there is no coordinating group with overall NPMP management responsibilities and authority, program continuity and accountability do not--and, indeed, cannot be expected to--exist.

The Battelle report also criticized the time lags, which sometimes have been as long as three to four years, between the collection of monitoring data and the compilation, evaluation, and publication of these data. A report by the National Agricultural Chemicals Association on the first 10 years of NPMP operation (Spencer 1974) makes a similar criticism of the NPMP.

The effort to develop or maintain an effective interagency organization concerned with pest control has a long and uneven history (see Chapter 3 of this report). If monitoring of pesticide residues is to be done in an orderly and systematic way, it is clearly necessary for EPA to assume the central responsibility

that it was given under FIFRA, as amended, to implement a national pesticide monitoring plan. It is unrealistic, however, to expect that EPA can or should take over all monitoring activities that are now being carried on by federal agencies. These agencies are certain to continue addressing their individually mandated responsibilities for monitoring pesticide residues, and they are unlikely to yield to any displacement in such activities by EPA. EPA's goals should be the reasonable ones of coordination in program planning, identification of data requirements, establishment of quality control for analytical techniques, and the establishment of a formal reporting mechanism for the data that are drawn from monitoring programs.

In identifying its data requirements in relation to pesticide residues, EPA should include not only monitoring data but also other relevant data, such as reports (for instance, National Cancer Institute [1975]) on the geographical and occupational frequencies of cancer in the United States that might indicate the possibility of some linkages with the presence of a pesticide chemical in a particular region or work site.

Recommendation

- EPA should accept and act upon its statutory responsibility for the implementation of a National Pesticide Monitoring Plan by determining the data that are needed for the regulation of pesticides and by exerting leadership among the federal agencies with monitoring programs to assure that the NPMP adequately addresses these needs.

Some steps have been taken in this direction. In 1975, the EPA Office of Pesticide Programs prepared a national pesticide mointoring plan that calls for the development of monitoring "networks" and of a centralized system for handling data. The proposed networks include existing federal monitoring programs, any new programs that may be required, and the integration of regional and state monitoring programs when their designs and analytical methodologies are compatible with those of the national programs. EPA has revised its draft of the plan a number of times in response to comments from other federal agencies. The

latest version of the plan was submitted to these agencies in March 1977.

The Pesticides Monitoring Journal

The Pesticides Monitoring Journal has served as a vehicle for distributing scientific and technical information gathered from pesticide monitoring programs. It is published quarterly under the auspices of the Federal Working Group on Pest Management (FWGPM), which is responsible to the Council on Environmental Quality. When the FWGPM become inactive after the dissolution of its secretariat (see Chapter 3 of this report), EPA took over the editorial responsibilities for the Journal.

The Journal has not only published the NPMP findings but has been an outlet for the results of other studies of pesticide residues. During the period when the FWGPM had the editorial responsibility for the Journal, there was extensive scientific peer review of the contents before their publication and there were rigorous requirements for the validity of the chemical analytical methodologies used in the studies for which data were reported. As a result of funding limitations, EPA has been unable to continue the prepublication peer review, although some technical opinions are still obtained from outside the OPP Technical Services Division, where the Journal is now produced.

To maintain its credibility and value, the Journal should reestablish rigorous requirements for the presentation of data on residue sampling. A board made up of analytical chemists whose work is concerned with pesticides should be responsible for reviewing the chemical methodology in each study that is reported. This board should include chemists who are experienced in the analysis of different substrates because analytical procedures differ widely, particularly in sample preparation. Additional reviewers, including biological scientists and other persons drawn from the scientific community in the manner usually employed by technical journals, should review the sampling plan, statistical validity, interpretation, and other technical aspects of each study that is reported in the Journal.

Recommendation

- EPA should adopt an editorial policy for the "Pesticides Monitoring Journal" that represents the highest scientific standards of data reporting and analysis and should make rigorous requirements for the explicit description of analytical methodologies in "Journal" articles.

NOTES

1 Abel, F.H. (1976) The Use of Economic Information in Registering Pesticides. An analysis of the role of economics and economic data in pesticide decision making from the perspective of the law, the regulations, and EPA procedures. (Unpublished paper prepared for the Committee on Pesticide Decision Making.)

2 Duggan, R.E. and M.B. Duggan (1976) Definition and Classification of Food and Food Groups for the Purpose of Codex Tolerances for Pesticide Residues. A report prepared for the Food and Agriculture Organization of the United Nations. ESN 0107-75-06. (Working document only.)

CHAPTER 3

COORDINATION AND COMMUNICATION OF INFORMATION ON PESTICIDES

INFORMATION REQUIREMENTS

The information needed by EPA for the regulation of pesticides originates in a number of disciplines and comes from a broad spectrum of agricultural, forestry, industrial, environmental, and health interests. It must cover not only the toxic effects that may occur in humans, wildlife, or farm animals as a result of pesticide use but also the economic and agricultural effects of a pesticide and of substitute chemicals or alternative pest control methods. The sources of these data are varied and include field experience in the use of various pest control measures on crops, surveys to obtain quantitative information on the use of pesticide chemicals, and laboratory tests.

To ensure consumer protection and environmental quality, EPA requires extensive testing of pesticides before they can be registered and marketed. Although the Agency independently tests certain kinds of products and validates testing systems, it lacks adequate resources to test all of the products for which toxicological studies are required. In the case of pesticides, the responsibility for such testing is assigned by law to the manufacturer. Under FIFRA, as amended, the adequacy and validity of laboratory and field tests essentially remain the responsibility of the product sponsor as part of the process of establishing the marketability of a pesticide. EPA guidelines outline the type and extent of testing that is required to determine the safety and utility of a product, and the results of these studies must be submitted to EPA before a product can be registered and sold.

Because the manufacturer or processor of a pesticide bears the burden of proof for establishing the pesticide's efficacy and safety, the EPA function

is primarily one of review and response to information submitted by an interested party. This is a complex and difficult assignment because it must mesh with the Agency's responsibility to protect humans and the environment from unreasonable adverse effects stemming from the use of pesticides. To make appropriate judgments about a pesticide, EPA must have both the scientific capability to assess the data submitted by industry and a ready access to independent data and other information that are relevant to each pesticide that is under review.

The importance of data and other information from independent sources was made evident by John R. Quarles, Jr., then Deputy Administrator of EPA, in testimony on pesticide safety testing before a joint hearing on January 20, 1976 of the Subcommittee on Administrative Practice and Procedure of the Senate Judiciary Committee and the Subcommittee on Health of the Senate Committee on Labor and Public Welfare. Mr. Quarles said that, although private laboratories which do research on pesticide chemicals for industry "generally provide competent and honest services, there are indications that serious problems may exist." He said that four improper situations are possible:

> ...a laboratory could be technically incompetent to perform the test, due to an inadequacy of personnel, essential equipment or management experience. Second, valid test results indicating dangerous pesticide characteristics may be withheld from EPA. Third, a laboratory might be so dependent upon a pesticide producer for contract work that its independent scientific judgment could be impaired by the close economic relationship. And fourth, a laboratory might intentionally misrepresent test results at the request of the manufacturer.

Mr. Quarles also described a specific situation of this kind that had occurred:

> For example, in recent EPA administrative hearings on Heptachlor/Chlordane and Aldrin/Dieldrin, we found that many of the laboratories which had completed chronic toxicity studies performed extremely conservative histologic examinations. In virtually every instance, independent pathologists diagnosed many more cancerous and

precancerous tumors in the test animals than did the original laboratory pathologists.

The integrity of independent laboratories is essential. If objective judgment is impaired by the dependence on future contracts, then the test results would be in question whether the funding came from pesticide manufacturers or from EPA.

EPA's needs for adequate data have been considerably enlarged by the Congressional requirement that, in addition to acting on new applications for pesticide registration, EPA must review about 33,000 registered pesticide products which were approved before the enactment of the FIFRA amendments. EPA is also reviewing some 4000 tolerances for pesticide residues. The reviews of older pesticide products have shown that, in many cases, the testing that was done in order to obtain registration of those products in past years is now inadequate in terms of present scientific testing standards and statutory requirements. Agency problems in reevaluating such data, particularly in areas where there are indications that a pesticide chemical may have oncogenic effects, have resulted in EPA halting its registration and reregistration of pesticides. (See Chapter 2 for a more detailed account of the problem.)

Credibility of Information

The testing required for pesticides is established by EPA's basic legislation, by its regulations, and by the available technology to fulfill these requirements. The laboratory data required by EPA in the pesticide program are primarily intended to assess the acute, subchronic, and chronic toxicity of a pesticide product to humans or to animals, including any reproductive, teratogenic, carcinogenic, mutagenic, or degenerative effects, based upon the appearance of these effects in laboratory animals. Data may be derived from *in vivo* or *in vitro* tests, and these laboratory investigations may involve biochemistry, nutrition, immunology, microbiology, and other disciplines. The importance of toxicological and other test data in EPA decisions on the safety and efficacy of pesticide products demands protocols and procedures in these studies that are scientifically sound and that will ensure the quality and integrity of the data.

Although the laboratories of pesticide manufacturers and those of research or testing firms

that are under contract to applicants for pesticide registration or reregistration do most of the data development relating to the safety and efficacy of pesticides, some data submitted to EPA in support of pesticide products are derived from studies made by veterinary and medical clinics, hospitals, universities, State Agricultural Experiment Stations, and the research laboratories of government agencies or their contractors. The facilities where these studies are done range from those of large corporations to laboratories in which a few people study a pesticide chemical for a sponsoring firm or institution. The EPA Office of Pesticide Programs also maintains laboratories, which provide support for Agency reviews and other regulatory functions relating to pesticides. Six of the laboratories are located in EPA facilities in Beltsville, Maryland and three are in Corvallis, Oregon. These laboratories, which are administered by the OPP Technical Services Division, specialize in the following areas: (in Beltsville) microbiology, entomology, plant biology, animal biology, pharmacology, and chemistry; (in Corvallis) plant biology, anti-fouling (the control of organisms that foul boat hulls and marine structures and equipment), and entomology (personal communication from Dr. William S. Murray, Director, OPP Technical Services Division).

Because EPA must place great reliance in its decision making on data that have been submitted by applicants, there must be confidence in the Agency's ability to determine that these data have quality and integrity. To meet this objective, it is important for EPA to have a quality assurance program. A basic method for obtaining data that have scientific validity is to establish standards for testing pesticide products which define the required reliability and precision of the analytical systems used in the tests of pesticide products. OPP publishes two procedural manuals, one on chemical and the other on biological methods, that are updated regularly and are available to laboratories that do pesticide analyses. In effect, these manuals serve as standards and they are used in the Agency's legal proceedings for pesticide products. OPP also tries to improve the quality of data on pesticides by providing some technical advice, covering a wide range of disciplines, to regional, state, and university laboratories that analyze pesticide products.

It is also necessary to incorporate quality standards for data in the Agency's published guidelines that specify the kinds of information that must be

submitted for the registration or reregistration of a pesticide. EPA has published in the Federal Register (U.S. EPA 1975) its proposed guidelines on Agency requirements in the following areas: test procedures to establish the effectiveness and usefulness of the different categories of proposed pesticides; the development of claims for a pesticide label; information on the chemistry of a pesticide product, and the fate and movement of the pesticide in the environment; and the collection and reporting of data on the toxicity of the pesticide. The proposed guidelines are being reviewed by the EPA Scientific Advisory Panel and revisions in the procedures will incorporate the recommendations of this group. EPA stated, in publishing its proposals, that the guidelines are not intended to be static and will be modified or expanded as new scientific information becomes available. The Agency has not yet published its guidelines for a number of other important areas in pesticide regulation: registration procedures; experimental use permits; petitions for tolerances; and packaging, storage, and disposal methods.

To help in determining the quality of data that have been submitted in support of pesticide products, it is important for EPA to contract for independent research that covers all pertinent categories of toxicological testing, such as long-term feeding tests for chronic effects, short-term feeding tests for acute effects, short-term screening tests, reproduction and teratology tests, and tests for mutagenicity. In addition, the Agency should accelerate its efforts to collect valid data in a computerized system that would make data readily available for all regulatory needs in the control of pesticides. This data system should include information on alternative pest control measures and on the economics and benefits of various pest control technologies. This information is needed by the Agency for risk/benefit assessments. A high level of support within EPA will be necessary to establish a dependable system for the retrieval of current, relevant, and reliable data on pesticide chemicals because building such a system will be a difficult and costly undertaking.

Recommendation

- OPP should take the lead in developing a modern data system to identify important sources of scientific and technical information on pesticides and to provide a

reliable method for collecting, evaluating, validating, indexing, and computerizing data on pesticides.

Intra-agency Considerations

To learn more about EPA's needs for data and the Agency's use of scientific and technical information in its decision making, this Committee explored two areas in some detail. One was the Rebuttable Presumption Against Registration (RPAR) process described in the Cancellation/Suspension section of Chapter 2 in this report. Another was EPA's use of information in setting tolerance levels for pesticide residues. The latter, which is described briefly here, indicates that better coordination and communication of information on pesticides is vital to the Agency if it is to lessen its dependence on information from its applicants and petitioners.

The Federal Food, Drug, and Cosmetic Act specifies the information that must be submitted with a petition for the establishment of a tolerance for residues of a pesticide chemical. This information must include the chemical identity and composition of the pesticide; information on its use; full reports of investigations of the pesticide's safety; the results of tests on the amount of residue and a description of the analytical methods used; the proposed tolerance; and practicable methods for removing residues that exceed this tolerance. Data provided by the petitioner are then reviewed by the Chemistry, the Toxicology, and the Efficacy and Ecological Effects Branches of the OPP Registration Division.

The Chemistry Branch has been using a set of informal guidelines that were first developed when the Food and Drug Administration was responsible for setting tolerances for pesticide residues and that are periodically updated by EPA. These guidelines offer petitioners for tolerances a detailed description of the information that is required to support a proposed tolerance. The reviewing chemists in the OPP Chemistry Branch also use the guidelines to determine whether the kinds of data that are submitted are appropriate. The ability of reviewers to evaluate the data can often be limited by a lack of current and relevant information in the scientific literature. This problem is accentuated in the case of new candidates for pesticides because there is no field experience to draw upon in evaluating these products. Furthermore, it is

likely that the only studies of the metabolic routes of a new pesticide in crops and animals were made by the petitioner or by the petitioner's contractor. Because these studies are held in confidence until presented to EPA, the data are not available in scientific literature, where they might be assessed and commented on by the larger scientific community. However, in cases where a petitioner seeks to establish tolerances for an approved pesticide on additional crops, or when a pesticide is related in some other way to pesticides for which tolerance levels have been established, a reviewer can compare the data for the registered and the proposed uses. There may also be pertinent information in the scientific literature which will be useful to reviewers in such instances.

In addition to assessing the petitioner's data, reviewers must determine whether the assay method used by the petitioner to identify and quantify the estimates of chemical residues is an adequate one. This judgment is aided by the results of residue recovery studies done in the laboratory section of the Chemistry Branch. These recovery studies are somewhat limited, however, by a lack of equipment and trained personnel to determine the extraction efficiency of an assay method for aged and weathered residues that are present on crops when they are harvested.

The Toxicology Branch of the OPP Registration Division also uses an informal set of guidelines that were developed by the Food and Drug Administration and that have been updated to take account of changes in standards for toxicological testing. Like their co-workers in the Chemistry Branch, the Toxicology Branch reviewers are handicapped by the fact that most of the data available to them on the toxic effects of a pesticide are provided by an interested party. However, they do have access to some independent studies of chemical toxicity, including studies by the National Cancer Institute, of the oncogenic effects of a number of pesticides for which residue tolerances have been set. These studies, which take two to three years, may be helpful to reviewers in the Toxicology Branch when they have been made of chemicals that are closely related to a candidate for a tolerance. For short-term studies of the acute toxic effects of a pesticide, reviewers in the Toxicology Branch are able to use laboratories operated by the OPP Technical Services Division.

The Efficacy and Ecological Effects Branch of the OPP Registration Division is concerned with any adverse

effects of pesticides on humans or the environment and with the efficacy of new pesticide products. Reviewers proceed on the basis of their own background and experience, consultation with their associates in other OPP units, the EPA regulations, and the Interim EPA Guidelines for Suspected Carcinogens.

In addition to the problem of relying almost solely upon data from petitioners for residue tolerances, personnel in the three branches of the OPP Registration Division commented, in remarks to the Committee on Pesticide Decision Making and its staff, that there were problems of poor communications with personnel in the OPP Criteria and Evaluation Division and that they did not receive much cooperation from the EPA Office of Research and Development (ORD). There also seems to be limited coordination between the OPP branches that review pesticide applications and the Pesticides and Toxic Substances Enforcement Division of the EPA Office of General Enforcement. There is somewhat better coordination between the OPP branches and the Pesticide Misuse Review Committee (PMRC) in that office. The PMRC provides information to EPA headquarters on concurrence with regional enforcement actions, develops guidelines for handling cases in which pesticides have been misused, studies patterns of misuse, and determines whether the labeling and packaging of pesticides are adequate. As a result of its reviews of cases in which pesticides have been misused, the PMRC has made 17 recommendations on labeling to the Registration Division which will be incorporated in the reregistration process for those products.

Recommendation

- OPP should develop and utilize an internal communications system which will give all OPP divisions an effective role in the decision-making process.

SOURCES AND DISTRIBUTORS OF PESTICIDE INFORMATION

Information about pesticide chemicals is dispersed among regulators, producers, and users of pesticides, medical scientists and researchers, fish and game commissions, agricultural research stations, state extension services, and other agencies and groups. These form a loosely constructed information network that can be a valuable resource for EPA to draw upon in the regulation of pesticides and can serve as a

mechanism for the dispersion of information on EPA decisions. If this network is to be effective in these roles, however, it must be able to communicate rapidly with EPA on such matters as the availability of pesticides, the cancellation of pesticide registrations, changes in pesticide labeling, emergency pest control needs, requirements, and problems that arise in the use of specific pesticides.

U.S. Department of Agriculture

EPA is required by FIFRA, as amended, to notify the Secretary of Agriculture at least 60 days before issuing a notice of intent to cancel a registration, to change its classification, or to hold a hearing on a pesticide. Except for this relationship that has been established by Congress, EPA and USDA did not develop a formal arrangement for the exchange of information until recently, although there have been continuing communications on a personal level between employees of the two agencies. A good beginning toward the establishment of closer relationships was made in the memorandum of understanding that was signed by the agencies in December 1976. This document establishes an administrative mechanism for gathering and assessing information to be used in making benefit/risk assessments in the EPA Rebuttable Presumption Against Registration (RPAR) process and it represents an effort to implement the legislative mandate regarding changes in classification or cancellations of pesticides (see Chapter 2 of this report for more detail on the memorandum).

USDA has extensive scientific and technical information on the use of pesticides and is a major resource for much of the data that EPA needs to carry out its regulatory functions in this area. The USDA Current Research Information System (CRIS), for example, could be used by EPA to obtain detailed data on the pest control needs and practices of farmers, the use of pesticides in forestry, and other pertinent statistical information.

Recommendation

- The cooperative action undertaken by EPA and USDA on benefit/risk assessments should be broadened so that EPA has ready and regular access to the extensive data resources of USDA on all aspects of pest management. For

example, EPA should work with USDA to develop and conduct a survey, preferably on an annual basis, of the nation's use of pesticides.

Other Federal Agencies

The U.S. Department of Health, Education, and Welfare has been important to EPA as a source of scientific and technical information on the health aspects of pesticide use and regulation. The Toxicology Branch of the OPP Registration Division, for example, has used oncological studies by the National Cancer Institute of several registered pesticides and has benefited from communications with the Food and Drug Administration and the Public Health Service of HEW.

Interagency Relationships

Since 1940, attempts have been made to establish regular communications among federal agencies on the safe and effective use of pesticides, on research in this area, and on federal pest control programs. Various formal interdepartmental groups were set up for this purpose, each displacing an earlier group in an attempt to develop effective working relationships in the pest control sector. The sequence of groups established for this purpose was: the Interdepartmental Committee on Pest Control, the Federal Pest Control Review Board, the Federal Committee on Pest Control, and a subcommittee on pesticides of the Committee on the Environment. Finally, the Federal Working Group on Pest Management (FWGPM) was set up in 1970 under the Council on Environmental Quality with the responsibility of reviewing and coordinating the proposed pest control programs of its member federal agencies. A secretariat of seven persons, the functioning arm of the FWGPM, was supported by EPA until the secretariat was dissolved in June 1976 as the result of a recommendation by the Office of Management and Budget; the FWGPM has been inactive since that time. The lack of a formal communications network on pest control at the federal level could inhibit the flow of information between EPA and other federal agencies whose research or other functions relate to EPA concerns.

One formal interagency organization that was recently established is the National Center for Toxicological Research in Jefferson, Arkansas, which is

funded jointly by EPA and the Food and Drug Administration. The center has begun doing research on carcinogenicity and teratogenicity at the low levels corresponding to most human exposures to pesticide chemicals and is beginning to be a valuable source of this information for EPA decision making.

State Agencies

A number of state agencies are directly involved with pesticides in their regulatory, research, educational, or administrative functions. Many states have passed enabling legislation for state regulation of pesticides and for the implementation of programs consistent with the state's particular needs. In states that have effective regulatory programs, the knowledge of personnel in the regulatory agency--in most cases this is the state department of agriculture--can be a valuable asset that should be used by EPA in its decision making on pesticides. Program capabilities of the regulatory agency still need to be developed or strengthened, however, in a number of states that have enacted legislation for pesticide regulation. Other states have not assumed responsibility for the regulation of pesticides because of limited resources, a lack of critical need, or lobbying by affected groups.

Recommendation

- State agencies regulating the registration, distribution, and use of pesticides should have a formal liaison, either through a state advisory board for pesticide regulation or through a memorandum of agreement, with these groups: the State Agricultural Experiment Stations; State Cooperative Extension Services; other state agencies; industry and trade associations; and public health, environmental, and user groups.

It is difficult to quantify the knowledge of pesticides in state agencies such as the State Agricultural Experiment Stations, which do research in agriculture; the State Cooperative Extension Services, whose functions are primarily educational; and public health agencies; departments of natural resources; and fish and wildlife commissions. One measure that might be used is the amount of money spent for research on

pest control by some of the agencies at the state level. A study by the National Academy of Sciences (NRC 1975b) reported that in 1972 more than $130 million were spent for this purpose by USDA's Agricultural Research Service and Forest Service, the State Agricultural Experiment Stations, forestry schools, and cooperating institutions. Other state agencies, such as the State Cooperative Extension Services, have had considerable field experience in the use of pesticides. These agencies are particularly important to EPA because they constitute part of the network for information on pesticide regulatory decisions that is in direct communication with the users of pesticides, local farm and labor organizations, and trade associations.

The importance and effectiveness of state agencies in pesticide decision making was demonstrated in 1970 when growers in the northwest United States noticed the appearance of a new insect pest in forage grasses, which were being destroyed by insect larvae. The State Agricultural Extension Service quickly identified the troublesome insect as the crane fly, a recognized problem in Canada, but not in the United States. There was no pesticide registered in the United States for control of the crane fly at that time, but with information from its counterpart in Canada, the Extension Service did field tests of a number of pesticides and helped to obtain registration for the use of methyl parathion to control this pest on forage grasses.

State agencies may also be more aware than a federal regulatory agency of the possible risks in the use of a pesticide because they are closer to these problems. This is illustrated by another example of action that was taken by a state agency. In the late 1960s, there were many complaints that ornamental trees were showing signs of damage. Upon investigation, a state agency determined that these injuries resulted from applications of "weed and feed" herbicide products containing dicamba. The label for these products, which were being applied to lawns, did not contain a warning against applications within the dripline or root zones of trees and shrubs. After research confirmed the fact that applications of the chemical were injuring these plants, the registrants of the pesticides were notified of the problem and the necessary warnings were then placed on the products.

Despite the knowledge of pesticides at the state level, and the needs at this level for information on

EPA's decisions relating to pesticides, communications between EPA and state agencies seem to be poor. In comments made to the Committee on Pesticide Decision Making, officials of the State Agricultural Experiment Stations and State Cooperative Extension Services said that EPA does not seem to be aware of the expertise and the scientific and technical information that are available in the states. They also said that the flow of information from EPA to the states is seriously inadequate. It sometimes takes months before information about EPA decisions for specific pesticides reaches the State Cooperative Extension Services and, in many cases, an Extension Service pest management specialist first learns from a source in industry about an EPA action that affects what the specialist is demonstrating to farmers for the control of a particular pest. Agency officials reported that frequent EPA changes in its regulations and the inability of users to get current information have caused so much delay in the public information programs carried on by State Cooperative Extension Services that these programs have lost some of their impact and credibility with the users of pesticides.

People who use pesticides need precise and timely information about these chemicals. The directions for pesticide use and the educational materials prepared by State Cooperative Extension Services and other agencies must be specific, accurate, and up-to-date. Furthermore, users of pesticides need to be kept informed of current and potential problems associated with pesticides and their options for solving these problems. For these reasons, it is imperative that regulatory officials, researchers, State Cooperative Extension Service specialists, and other concerned people at the state level should have ready access to current EPA actions in regard to pesticide registration, reregistration, and setting of residue tolerances.

Some communication between EPA and state groups is provided by the EPA State-Federal FIFRA Implementation Advisory Committee and, to a lesser degree, by the EPA Administrator's Pesticide Policy Advisory Committee and the formal commentary mechanism that accompanies federal rule-making. Participation by EPA scientists and other professionals in state, regional, and national meetings of professional organizations would also facilitate state-federal communications on the regulation of pesticides.

The microfiche system now being developed by EPA should provide much of the information on a product-by-product basis that is required to satisfy the needs of user groups. This system is too complex and cumbersome for general use, however, and it will be necessary for states or regions to develop guides that are based on the microfiche information for use by the public.

Recommendation

- In cooperation with the State-Federal FIFRA Implementation Advisory Committee, EPA should develop and implement a reference system that would give State Agricultural Extension Services, state regulatory agencies, pesticide users, and other concerned groups immediate access to information on current EPA registrations.

Surveys of Pesticide Use

Under earlier legislation on pesticides, it was not necessary to identify and quantify the benefits to be derived from the use of a pesticide or to develop data to measure potential losses that might result from cancellation of an effective pesticide product. These data are required by provisions of FIFRA, as amended, and they must enter into decisions made by the EPA Administrator to cancel or change the use of a pesticide.

Good published data on the use of pesticides that would help in assessing benefits, or the potential losses when a pesticide is cancelled, are relatively scarce. To obtain information of this type, the USDA Economic Research Service has done some sample surveys on farmers' use of pesticides in different regions of the United States and for different crops and classes of livestock. The most recent survey, in which 8600 farmers in 49 states were interviewed, was made of farmers' use of pesticides in 1971. Three reports on the survey cover the quantities of pesticides used, identified by the type of active ingredient; the extent of use, in terms of acreage and specific crops; and expenditures for pesticides, by type of crop and by level of gross farm sales (USDA 1975). A similar USDA survey that has not yet been published was made in 1976.

Four midwestern states did detailed studies in 1969 and 1970 of the use of pesticides on farms. Minnesota is the only one of these states that has continued to fund and conduct such surveys. The most recent Minnesota survey, which was made by the Minnesota Department of Agriculture in cooperation with the USDA Statistical Reporting Service, gathered information for 1974 on acreage treated with pesticides by major crop and chemical; acreage harvested; category of applicant (farmer or custom applicator); method of application; relative effectiveness of the pesticide; rates of pesticide application; the use of pesticides on specialty crops; and estimated costs of losses due to insects on untreated acreage (Minnesota Department of Agriculture 1975).

The value of surveys of this kind is that they are based on experience with the use of pesticides rather than on estimates or other information of a more general nature. Good data on field experience with pesticides can be used for the following purposes:

- to help analyze the benefits and risks involved in the use of pesticides;
- to determine the long-term distribution of pesticides and the chemical load in the environment;
- to correlate the application rate and frequency of pesticide use with the monitoring of pesticide residues;
- to evaluate integrated pest management procedures;
- to enable State Cooperative Extension Services to direct their educational programs to specific needs;
- to assess needs for training and certifying pesticide applicators;
- to assess the total economic and energy costs of pest control;
- to plan research priorities and needs; and
- to project the annual demand for chemicals and spray equipment.

Monitoring Programs

The National Pesticide Monitoring Program (NPMP), described in Chapter 2, has the potential for providing valuable data on residues of pesticide chemicals in humans, in wildlife, and in the environment. The limited funding and the diverse interests and responsibilities in this program, have inhibited its development and its use as a major source of data for the regulation of pesticides.

CHAPTER 4

PERSONNEL FOR PESTICIDE REGULATION

The implementation of pesticide legislation by the EPA Office of Pesticide Programs depends in large measure upon the skills, quality, distribution, size, and flexibility of its professional staff. The Committee found it difficult to assess these personnel factors in the OPP, however, because that office was considering various proposals for realignment of job functions while this study was underway.

It was also difficult for the Committee to determine the exact relationship between specific occupational functions in the Agency and the impact of these functions on final decisions that are made about pesticides. Throughout the entire Committee study, however, it was apparent that decision making on pesticides is a complex process that is highly dependent upon a variety of scientific, technical, and administrative skills. Public opinion often assigns to lawyers a primary role in the decisions that are made by regulatory agencies, possibly as a result of newspaper stories about the adjudicatory proceedings in these agencies. Furthermore, tenable evidence to support the actions of a regulatory agency is, appropriately, a matter of legal concern once this evidence has been developed by other personnel. It was evident during the course of this study, however, that EPA relies heavily upon the information and knowledge of scientists and technicians to determine whether the use of a particular pesticide is safe or if it appears to meet or exceed the criteria that the Agency has established to determine the presence of hazards to humans or to the environment. It seems reasonable to assume that decisions to issue notices of intent to cancel, suspend, or to change the use of a pesticide, and other major decisions of the Agency are shaped by the information that has been developed by scientists, technicians, and administrators at every stage of pesticide regulation.

The distribution of scientific and technical personnel at various levels is also of interest in assessing the relative importance the Agency gives to different types of knowledge and skills. Although this study focuses on the Office of Pesticide Programs and not on EPA as a whole, it seems likely that the distribution of personnel is somewhat similar throughout EPA. Data compiled by the NRC Committee for Study of Environmental Manpower (NRC 1977b) indicate that:

- EPA employs 43 percent of its 10,000 full-time, white-collar personnel in scientific and engineering categories, a higher proportion than in most government agencies.

- Scientists and engineers make up a large proportion of EPA personnel at top and middle levels of the Agency (scientists represent 65 percent and engineers represent 5 percent of the Civil Service "supergrade" employees of EPA in grade levels 16 to 18 and earn $39,629 to $54,410; at the middle management level, scientists have 32 percent of the positions in grades 12 to 15, and earn $20,442 to $43,923, while engineers have 27 percent of the jobs at this level).

- The educational level of EPA personnel is high, with 6 percent having Ph.D. degrees and 19 percent having master's degrees.

A detailed analysis of the professional employment in the various OPP divisions (excluding OSPR) as of February 1976 provides information on the distribution of professional personnel in these divisions.[1] Table 4.1 shows the distribution of scientific and tehnical positions in OPP by broad position categories, and Table 4.2 shows the distribution of these jobs by specific position description.

In its examination of the distribution of OPP personnel, the Committee concluded that there are not enough top-level positions for scientists in the OPP divisions. It is the opinion of this Committee that each major OPP division should add at least one senior scientist with responsibility for organizing and evaluating the work of these divisions. Additional scientists also are needed in a number of other occupational categories.

TABLE 4.1 Distribution of Scientific and Technical Positions in Office of Pesticide Programs, by Position Category, February 1976[1]

Position Category	Number of Positions	Percent
Administrative	94	22
Biological Sciences	125	29
Physical Sciences	79	18
Information	28	6
Social Sciences	14	3
Computer Sciences	13	3
Environmental Sciences	12	3
Medical Sciences	9	2
Mathematical & Statistical Sciences	6	1
Legal	2	1
Other	53	12
Total	435	100

[1] Excludes positions in the Office of Special Pesticide Reviews, which was being restructured when this study was underway.

SOURCE: U.S. EPA (1976) Organization and Staff, Office of Water and Hazardous Materials. Unpublished document.

TABLE 4.2 Distribution of Scientific and Technical Positions in Office of Pesticide Programs, by Position Description, February 1976[1]

Position Description	Number of Positions
Administrative	94
Biological Sciences	
Zoologist	2
Pharmacologist	10
Biologist	24
Physiologist	3
Entomologist	21
Fisheries biologist	6
Agronomist	7
Microbiologist	15
Plant pathologist	8
Plant physiologist	10
Biological technician	11
Botanist	1
Toxicologist	1
Human genetics specialist	1
Wildlife biologist	1
Animal biologist	1
Coordinator, biological methods	1
Agricultural research technician	2
Physical Sciences	
Chemist	68
Physical science technician	8
Physical science aide	3
Information	
Writer-editor	12
Technical information specialist	9
Management information specialist	1
Editorial assistant	1
Science writer	1
Technical information assistant	3
Library technician	1
Social Sciences	
Economist	12
Sociologist	2

TABLE 4.2 Continued

Position Descriptions	Number of Positions
Computer Sciences	
Computer systems analyst	4
Computer programer	4
Computer technician	3
Computer systems operator	1
Computer aide	1
Environmental Sciences	
Environmentalist	2
Ecologist	6
Environmental specialist	3
Systems ecologist	1
Medical Sciences	
Health effects analyst	2
Veterinary medical officer	1
Pathologist	1
Entomologist	1
Coordinator, field studies	3
Public health educator	1
Mathematical & Statistical Sciences	
Operations research analyst	4
Biostatistician	1
Statistical assistant	1
Legal	
Legal assistant	2
Other	
Product manager	12
Pesticide product specialist	31
Pesticide technician	5
Standards and labeling officer	1
Special registrations officer	1
Research analyst	1
Chemical engineer	1
Research assistant	1
Total	435

[1] Excludes positions in the Office of Special Pesticide Reviews, which was being restructured when this study was underway.

SOURCE: U.S. EPA (1976) Organization and Staff, Office of Water and Hazardous Materials. Unpublished document.

Recommendation

- Each major OPP division should add at least one senior scientist to its staff; additional scientists also are needed to increase OPP effectiveness in several occupational categories, including toxicology, pathology, and the mathematical, statistical, environmental, agricultural, social, and computer sciences.

The fact that federal pay levels for scientists and technicians are competitive with the salaries these persons can obtain elsewhere may not be enough to attract additional scientists of high caliber. It is also important for EPA to improve the status of its scientists among their peers in the greater scientific community and to expand the opportunities for its scientists to keep up with developments in their specialized fields.

Recommendation

- EPA should expand the opportunities for its scientists to communicate with their peers in the greater scientific community by encouraging participation in scientific meetings and by increasing the opportunities for an exchange of scientists between EPA and universities and other institutions and agencies.

The coordination of scientific expertise within OPP also can help to give scientists an effective role in the regulation of pesticides. At present, both the OPP Registration Division and the Criteria and Evaluation Division perform major scientific analyses of a related nature that might be better coordinated if they were centralized within OPP. This might also help to improve communications between scientists who are doing research on pesticide chemicals and the staff who are involved in the RPAR process.

Recommendation

- In order to achieve greater coordination of scientific effort in the regulation of pesticides, OPP should consider combining the

scientific personnel now located in its Registration and its Criteria and Evaluation Divisions into a single group. OPP should also assign a highly qualified scientist in each OPP division to coordinate the scientific effort of that division with the work of scientists in other OPP divisions.

This coordination would enable scientists to work as a team, to plan and coordinate their work across the divisions of OPP, and to provide the EPA Deputy Assistant Administrator and the EPA Administrator with balanced scientific judgments for the regulation of pesticides.

NOTE

1 U.S. Environmental Protection Agency (1976) Organization and Staff, Office of Water and Hazardous Materials. Unpublished document.

CHAPTER 5

INTERNATIONAL IMPACT OF EPA PESTICIDE DECISIONS

INTRODUCTION

Section 17(d) of FIFRA, as amended, provides that the EPA Administrator shall participate and cooperate in international efforts to develop improved research and regulations on pesticides. This Committee thought it appropriate to investigate, within its limited time and resources, the impact of EPA pesticide decisions on other countries.

The attitudes and actions of many countries toward the regulation of pesticides are heavily influenced by legislation and regulations of the United States that govern the use of pesticides. This influence stems from the position of the United States as a country with a highly developed science and technology to serve as a base for pest control; an importer of large quantities of agricultural commodities; an exporter of large quantities of pesticides; and a country with great agricultural and other uses for pesticides and extensive federal experience in pesticide regulation. These factors tend to influence the attitude and actions toward pesticides in countries with less experience in this field and with fewer scientists and technicians to provide expertise for the regulation of pesticides.

EPA decisions to ban or restrict the use of a particular pesticide on the basis that it is hazardous to humans and to the environment are of great concern in other countries where the pesticide is still being used. People in those countries often fear that they are in imminent danger from the pesticide even when it is carefully used by an appropriate government agency to cope with a problem, such as an outbreak of vector-borne disease, that does pose an imminent danger to human beings. In many of these countries, it is assumed that the United States possesses preeminent

knowledge and judgment in the regulation and use of pesticides because we have extensive experience with pest control techniques; however, only certain portions of this knowledge are applicable to the situation in other countries. Although the fundamental principles of the chemistry and toxicology of compounds are universal, the environmental behavior of a chemical and its residues may vary from country to country, depending on climate, soils, and other conditions. Public health considerations and economic capabilities also differ among countries and must enter into the value judgments that are made about the optimum methods for pest control.

SUMMARY OF RESPONSES

To learn about the impact of EPA decisions on other countries, the Committee on Pesticide Decision Making made inquiries to the appropriate agency in each of 23 countries. These countries were selected on the basis of varying stages of economic development and their different environmental, agricultural, and public health concerns. Responses to the Committee's question on the impact of EPA regulatory actions were received from the following countries: Australia, Canada, Federal Republic of Germany, France, India, Mexico, the Netherlands, New Zealand, Pakistan, South Africa, Sweden, and the United Kingdom. The responses from these countries are on file at the Board on Agriculture and Renewable Resources, National Research Council, where they may be inspected by the public. The following section of this chapter summarizes the responses to the question: "What is the impact in your country of decisions made by the Office of Pesticide Programs of the U.S. Environmental Protection Agency?"

Australia

Residues of pesticides in meat and other food products that Australia ships to the United States must conform to tolerance levels for residues established by EPA. As a result, EPA decisions on tolerances strongly influence the use of pesticides in Australia.

The response to the Committee's question indicated that Australia would prefer to see the EPA adhere more closely to the residue limits that have been recommended by the Codex Committee on Pesticide Residues because these limits recognize the differing needs of participating nations. The Codex Committee, a

subsidiary body of the Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), proposes international tolerances for pesticide residues in specific foods.

Australia also said that it requires some chemicals in its agricultural production for which EPA has not set tolerances because these pesticides are not needed in the United States. The response indicated that Australian authorities were uncertain whether EPA would recognize the tolerances that Australia has set for these products in the absence of tolerances set by EPA.

Strong regulatory actions taken in the United States and in other developed nations spur public action groups in Australia to put pressure on the government, and this has sometimes made it difficult for Australian authorities to pursue what they believe to be a reasonable and appropriate course of action for their nation. Despite these pressures, Australia is phasing out the use of DDT rather than abruptly banning this chemical. Australia was one of the first countries in the world, however, to impose restrictions on the use of DDT.

U.S. actions on the cyclodiene compounds have had minimal impact. Aldrin and dieldrin are used to control pests that attack sugar cane and to control termites, but have few other uses. Chlordane is considered essential for control of ants at urban and industrial sites, but it has never had significant uses in agriculture. Heptachlor also is used mainly against termites and has limited use in agriculture.

Canada

Canadian authorities said in their response to the Committee that any action by the United States to restrict or ban a pesticide is immediately reported by the Canadian press and this elicits a prompt government response. In the case of EPA actions on DDT, aldrin, and dieldrin, Canada was forced to react on a crash basis rather than in a more organized way. The Canadian government has made a special effort since that time to anticipate EPA regulatory actions in order to minimize the economic impact in Canada from the loss of a useful pesticide. The Canadian authorities said that there is now excellent liaison between Canada and the United States in the area of pesticides.

Federal Republic of Germany

The German Federal Biological Institute closely monitors EPA decisions. Pesticides that are restricted or banned in the United States are frequently subject to similar actions in Germany, but it was not clear in the response to the Committee's question whether this occurred as a result of decisions that were made by EPA or because German authorities made the same decisions at about the same time.

The German authorities indicated that the EPA tolerances for pesticide residues affect German exports to the United States and that the maximum tolerance levels that are established for pesticide residues in Germany are based primarily upon the EPA levels.

France

When French authorities respond to requests for approval of pesticides that are manufactured in another country, they take EPA decisions on the pesticide into consideration. In addition, toxicological studies for these products are examined, additional information may be sought, records of biological effectiveness are considered, and tests are conducted in various regions to assess the use of a pesticide under different agronomical situations.

India

India's response to the Committee indicated that EPA decisions probably have little or no effect on the regulatory practices or availability of pesticides in India. For example, DDT and aldrin (but not dieldrin) are approved for use in that country. Pesticide residue levels, however, cannot exceed the limits set by EPA in the agricultural commodities that are shipped to the United States.

Mexico

Tolerance levels and safety periods for the time between application of insecticides and a harvest are regulated by the Mexican government's Department of Plant Health. The tolerance levels are in accordance with those established by EPA.

The Netherlands

The government of the Netherlands limited the use of DDT, aldrin, and dieldrin before it was aware of EPA actions on these compounds.

EPA's establishment of limits for pesticide residues in some instances has had an important economic effect in the Netherlands. Some of that country's exports have been denied entry to the United States because of their levels of pesticide residues, and the resulting need in the Netherlands to intensify control of these residues has resulted in higher prices for certain food products. The Netherlands authorities said that their two programs to monitor these pesticides are a direct consequence of EPA regulatory actions. One of the programs monitors these compounds in beef, veal, pork, and eggs; the other monitors the compounds in biological systems.

New Zealand

Because New Zealand depends primarily upon the sale of farm produce in its foreign exchange, EPA decisions on pesticides have great impact in that country. New Zealand authorities appear to disagree with the United States on the need to restrict the use of DDT, but they must observe the decisions we have made on this pesticide for products that are exported to this the United States. Other organochlorine insecticides are not used in agriculture, except for the use of BHC under permit.

New Zealand, like Australia, strongly supports the acceptance of international standards for tolerance levels as established by the FAO/WHO Codex Committee on Pesticide Residues.

Pakistan

BHC and DDT are the only pesticides that are manufactured in Pakistan, although other pesticides are imported by the government. These and other organochlorine compounds are now being used in Pakistan, although BHC and DDT were practically banned after EPA actions on these pesticides.

Some concern was expressed in the response from Pakistan about the effect of EPA decisions on countries

in Asia and Africa which now insist that the fruits and vegetables they import from Pakistan be "residue free."

South Africa

South Africa said that its agriculture depends upon export markets and that it must adhere to the tolerance levels for pesticide residues that are set by importing nations. The Embassy of South Africa also said in its response to the Committee:

> Action taken by the EPA has been followed with keen interest - on occasion with dismay and concern. So for instance DDT has been entirely withdrawn to protect our export market though there was no justification for withdrawal from an environmental or human body burden point of view. The same applies to a lesser extent to aldrin, dieldrin, heptachlor, and chlordane.

Sweden

EPA decisions on DDT, aldrin, and dieldrin had no effect upon Sweden's regulation of these pesticides because Sweden took similar actions at an earlier date. No information regarding other effects of EPA decisions on Sweden was available.

The United Kingdom

The United Kingdom controls the use of pesticides through the Pesticides Safety Precaution Scheme (PSPS), a nonstatutory arrangement that is formally agreed to by the government and by three industrial associations that represent pesticide manufacturers. Under the PSPS arrangement, manufacturers notify the government before marketing a new pesticide or before they suggest new uses for existing pesticides. In addition, several Acts of Parliament relate to the use and disposal of pesticides.

Apparently, the EPA decision to cancel uses of DDT, aldrin, and dieldrin had little effect on pesticide practices in the United Kingdom. Before EPA made its decisions on these pesticides, the United Kingdom had decided to keep these chemicals under review and to replace them with less persistent chemicals whenever

possible. Other effects of EPA actions in the United Kingdom were not learned.

INTERNATIONAL COOPERATION

Because the actions taken by the United States in the regulation of pesticides may have a great impact on other nations, it is important that EPA fully implement Section 17(d) of FIFRA, as amended, and cooperate in international efforts to control pests and to regulate the use of pesticides.

In this effort, EPA should bear in mind that conditions and needs for pest management may vary considerably from country to country. Crop and climatic differences, variations in soils and other geographic characteristics, health conditions, economic considerations, and many other factors must be taken into consideration.

A recent draft statement by the U.S. Agency for International Development on the environmental impact of proposals for pest management recognizes this need for international cooperation and the fact that needs and conditions may differ considerably from country to country.[1] The statement says:

> While AID and the U.S. Government are responsible for their programs in the pest management area, it must be recognized that the decisions regarding development policies and practices in the less developed countries (LDC's) lie with the sovereign governments of those nations. U.S. influence in these decisions varies from case to case, but in all instances must be exercised in a collaborative and sensitive style if we are to continue to be a welcome force for development.
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> Except in emergencies, AID will discourage requests for pesticides and the use of pesticides unless they are to be used in integrated pest management-crop production systems. If and where pesticides are supplied, regardless of whether purchased in the United States for export or purchased locally in less developed countries, their selection should not be governed entirely by domestic U.S. regulations, registrations, or restrictions, but by the needs of the

recipient country and the specific conditions in the country.

Recommendation

- EPA should ascertain the potential impact that its major regulatory actions may have on other countries through prior consultation with the Food and Agriculture Organization, the World Health Organization, and other appropriate international bodies. EPA also should work with the U.S. Department of State and other federal agencies to engage in cooperative activities with other nations for the development of effective programs for pest management and pesticide regulation.

NOTE

1 U.S. Agency for International Development (1976) Draft Environmental Impact Statement on the AID Pest Management Program. Volume 1 - Summary.

APPENDIX

The Committee on Pesticide Decision Making convened a workshop on August 18 and 19, 1976 on The Impact of EPA Pesticide Regulations and Decisions. The purpose of the workshop was to provide a public forum for the discussion of the impacts of recent pesticide regulations and decisions. Edward Glass was chairman of the organizing committee, which consisted of Perry Adkisson, Morris Cranmer, Joseph Headley, Lucille Stickel, and Dan Tarlock. Individual papers, authors, and discussants are listed below. Copies of the papers and the discussant remarks may be reviewed at the Board on Agriculture and Renewable Resources, National Academy of Sciences, Washington, D.C.

The Committee workshop covered these topics:

Purpose and Philosophy of Pesticide Laws and Regulations

John Osmun, Purdue University, West Lafayette, Indiana

Impact on Nontarget Areas--Residues in Soil, Water, and Air

Ronald J. Kuhr, New York State Agricultural Experiment Station, Geneva, New York

Discussant - Virgil H. Freed, Oregon State University, Corvallis, Oregon

Impact on Nontarget Areas--Biosystems

Eugene E. Kenaga, Dow Chemical Company, Midland, Michigan

Discussant - Tony J. Peterle, Ohio State University, Columbus, Ohio

Impact on Research and Development of Pesticides

K. Ross Fitzsimmons and Richard R. Whetstone, Shell Chemical Company, San Ramon, California

Discussant - Ely Swisher, Rohn & Haas Company, Philadelphia, Pennsylvania

Impact on the Use of Pesticides

Boysie Day, University of California, Berkeley, California

Discussant - Alexander C. Davis, New York State Agricultural Experiment Station, Geneva, New York

Impact on the Development of Integrated Pest Management

Robert P. Upchurch, University of Arizona, Tucson, Arizona

Discussant - L. Dale Newsom, Louisiana State University, Baton Rouge, Louisiana

Impact on Food and Fiber Production in the United States

J. Edward Swift and James Kendrick, University of California, Berkeley, California

Discussant - Fred H. Tschirley, Michigan State University, East Lansing, Michigan

Impact on FAO and on Food and Fiber Production in Developing Countries

William Furtick, Food & Agriculture Organization, Rome, Italy

Discussant - Ahmad S.K. Ghouri, Pest Management Research Council, Pakistan

Impact on European Plant Protection Organization and on Food Production in Industrialized Countries

Gus Mathys, European Plant Protection Organization, Paris, France

Discussant - Lucas Brader, Food & Agriculture Organization, Rome, Italy

Impact on Public Health in the United States

Maurice W. Provost, Florida State Board of Health, Vero Beach, Florida

Discussant - Morris F. Cranmer, National Center for Toxicological Research, Jefferson, Arkansas

Impact on International Health Organizations and Public Health in Foreign Countries

John F. Copplestone, World Health Organization, Geneva, Switzerland

Discussant - John E. Davies, University of Miami Medical School, Miami, Florida

Impact on Educational Institutions

Edward H. Smith and Charles E. Palm, Cornell University, Ithaca, New York

Discussant - Donald C. Peters, Oklahoma State University, Stillwater, Oklahoma

GLOSSARY

AID	U.S. Agency for International Development
CAG	Carcinogen Assessment Group of EPA
CRIS	Current Research Information System of USDA
CED	Criteria and Evaluation Division of OPP/EPA
EDF	Environmental Defense Fund
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization of the United Nations/World Health Organization
FDA	Food and Drug Administration of HEW
FEPCA	Federal Environmental Pesticide Control Act of 1972
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWGPM	Federal Working Group on Pest Management
GAO	U.S. General Accounting Office
HEW	U.S. Department of Health, Education, and Welfare
NPMP	National Pesticide Monitoring Program
NRC	National Research Council
OPP	Office of Pesticide Programs of EPA
ORD	Office of Research and Development of EPA
OSPR	Office of Special Pesticide Reviews of OPP/EPA
PCRC	Pesticide Chemical Review Committee of OPP/EPA
PEPS	Pesticide Enforcement Policy Statements
PMRC	Pesticide Misuse Review Committee of EPA
RPAR	Rebuttable Presumption Against Registration
SAES	State Agricultural Experiment Stations
SCES	State Cooperative Extension Services
USDA	U.S. Department of Agriculture

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